# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and	) REDACTED PUBLIC VERSION
SANOFI-AVENTIS US LLC,	)
Plaintiffs,	)
v.	) C.A. No. 06-286-GMS
BARR LABORATORIES, INC.,	)
Defendant.	)

# PLAINTIFFS' ANSWERING BRIEF OPPOSING BARR'S MOTION TO DISMISS OR BIFURCATE AND STAY DISCOVERY ON WILLFUL INFRINGEMENT CLAIM

Of Counsel:

Paul H. Berghoff
Joshua R. Rich
Jeremy E. Noe
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

Dated: June 28, 2006

ASHBY & GEDDES
Steven J. Balick (I.D.#2403)
John G. Day (I.D. #2114)
Tiffany Geyer Lydon (I.D. #3950)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
302-654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tlydon@ashby-geddes.com

Attorneys for Plaintiffs

# TABLE OF CONTENTS

Page

I.	INTI	RODUC	CTION	1	
II.		NATURE AND STAGE OF PROCEEDINGS 2			
III.		SUMMARY OF ARGUMENT			
IV.	FAC	ACTUAL BACKGROUND4			
V. ARGUMENT			Т	5	
	A.		Court Should Not Dismiss Sanofi-Aventis' Willful Infringement ms, Especially If Barr's Declaratory Judgment Counterclaims Remain  Willfulness Contentions Are Not Automatically Precluded in an ANDA Case, Particularly Where More Than Just a § 271(e)(2)  Act of Infringement May Be At Issue		
	В.	2.	It Is Premature to Rule Out the Possibility That Discovery May Produce Evidence of Willful Infringement		
	В.	Willf	Court Should Not Bifurcate and Stay Discovery on Plaintiffs' ful Infringement Claims  Defendants Would Not Be Severely Prejudiced By A Quantum Dilemma Because the Federal Circuit Now Holds That No Adverse Inference Flows From Failure to Produce an Opinion Of Counsel		
		2.	Bifurcation Would Be Judicially Inefficient And Would Prejudice Plaintiffs With The Need to Present Some Evidence Twice	12	
VI.	CON	CLUSIO	ON	11	

# TABLE OF AUTHORITIES

# **CASES**

Allergan, Inc. v. Alcon, Inc., CA No. 04-968 (GMS), 2005 WL 3971927 (D. Del. July 26, 2005)
Calmar, Inc. v. Emson Research, Inc., 850 F.Supp 861 (C.D. Cal. 1994)
Eisai Co., Ltd. v. Dr. Reddy's Labs. Ltd., C.A. 03-9053, Hearing Tr. (S.D.N.Y. Oct. 12, 2004)
Elvig v. Calvin Presbyterian Church, 375 F.3d 951 (9th Cir. 2004)
Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568 (Fed. Cir. 1988)
Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004)
Johns Hopkins Univ. v. Cellpro, 160 F.R.D. 30 (D. Del. 1995)
Kao Corp. v. Unilever United States, Inc., 334 F. Supp. 2d 527 (D. Del. 2004)
Kimberly-Clark Corp. v. James River Corp., 131 F.R.D. 607 (N.D. Ga. 1989)
Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337 (Fed. Cir. 2004)
Kos Pharm., Inc. v. Barr Labs., Inc., 218 F.R.D. 387 (S.D.N.Y. 2003)
Lis v. Robert Packer Hosp., 579 F.2d 819 (3d Cir. 1978)
Mellon v. Beecham Group PLC, 17 U.S.P.Q.2d 1149, Civ. No. 86-2179, 1991 WL 16494 (D.N.J. Jan. 3, 1990)11
Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., Civ. A. 05-CV-1887, 2005 WL 3664014 (D.N.J. Dec. 30, 2005)

Quantum Corp. v. Tandon Corp.,         940 F.2d 642 (Fed. Cir. 1991)       11
Real v. Bunn-O-Matic. Corp., 195 F.R.D. 618, 626 (N.D. III. 2000)
Ruiz v. A.B. Chance Co., 234 F.3d 654 (Fed. Cir. 2000)
Smith v. Alyeska Pipeline Serv. Co., 538 F.Supp. 977 (D. Del. 1982)
SmithKline & French Labs., Ltd. v. Teva Pharms., USA, Inc., C.A. No. 05-197-GMS, Hearing Tr. (D. Del. July 28, 2005)
Trading Technologies, Int'l, Inc. v. Espeed, Inc., F.Supp.2d, C.A. No. 04 C 5312-JBM, 2006 WL 1037322 (N.D. Ill. April 17, 2006)
Turbe v. Government of the Virgin Islands, 938 F.2d 427 (3d Cir. 1991)
Willemijn Houdstermaatchaapij BV v. Apollo Computer Inc., 707 F. Supp. 1429 (D. Del. 1989)
STATUTES AND REGULATIONS
21 U.S.C. § 355(j)(2)(A)6
21 U.S.C. § 355(j)(2)(A)(vii)(IV)
21 U.S.C. § 355(j)(2)(B)(iv)(II)5
35 U.S.C. § 271(e)(2)
Fed. R. Civ. P. 12(b)(6)
Fed. R. Civ. P. 12(c)
Fed. R. Civ. P. 12(h)(2)
Fed. R. Civ. P. 42(b)

#### I. INTRODUCTION

If this action was premised only on Barr's ANDA submission that seeks to market a generic triamcinolone acetonide nasal spray, Barr might have a colorable argument that Sanofi-Aventis could not sustain a willful infringement claim. However, Barr has sought to make the scope of this case far broader by including declaratory judgment counterclaims that cover actions well beyond the submission of its ANDA. Furthermore, this case is at a posture -- prior to the beginning of discovery -- at which this Court has established that a willfulness claim should be preserved to allow the plaintiff to seek information that would show willfulness based on more than merely the act of submitting an ANDA and Paragraph IV certification. Under these circumstances, none of the cases that Barr cites suggests that a willfulness claim should be stricken, and this Court's own decisions suggest that it should remain for discovery.

No precedent holds that a claim of willful infringement is never appropriate in an ANDA action. Especially where, as here, the pleadings indicate that more than just § 271(e)(2) acts of infringement may be at issue, *Glaxo* does not automatically preclude a claim of willful infringement. Numerous courts, including this Court, have permitted discovery seeking to support a theory of willful infringement based on a frivolous and wholly unjustified ANDA filing with Paragraph IV certification. It would be premature for this Court to foreclose Sanofi-Aventis from attempting to elicit facts sufficient to support a willful infringement claim. Accordingly, Sanofi-Aventis' willful infringement claim should not be dismissed.

Discovery relating to Sanofi-Aventis' willful infringement claim also should not be bifurcated and stayed. Bifurcation under Rule 42(b) is the exception, not the rule, and Barr has not satisfied its burden of establishing that bifurcation will promote judicial economy and will not unduly prejudice either party. Barr does not face a so-called "Quantum dilemma" absent bifurcation because the Federal Circuit has disposed of any adverse inference flowing from a party's election not to produce an exculpatory opinion of counsel. Because there is close overlap here between evidence of liability and willfulness, bifurcation would prejudice Sanofi-Aventis with the time and expense of presenting the same evidence twice. Accordingly, this Court should deny Barr's motion in the alternative to order bifurcation and stay discovery on willful infringement claims.

# II. NATURE AND STAGE OF PROCEEDINGS

On May 2, 2006, Plaintiffs Aventis Pharmaceuticals Inc. and Sanofi-Aventis US LLC (collectively "Sanofi-Aventis") brought this action against Defendant Barr Laboratories, Inc. ("Barr") for infringement of U.S. Patent Nos. 5,976,573 (D.I. 1, Ex.1) and 6,143,329 (D.I. 1, Ex. 2) ("patents-in-suit"). Barr infringed the patents-in-suit by submitting an ANDA with Paragraph IV certification that seeks FDA approval to market a triamcinolone acetonide aqueous nasal spray before expiration of the patents-in-suit. (D.I. 1, Compl. ¶ 14).

Barr filed an Answer and Counterclaims on May 22, 2006. (D.I. 6, Answer, at p.1). Barr's counterclaims included allegations that the actual manufacture, use, or sale of Barr's ANDA products would not infringe claims of the patents-in-suit. (D.I. 6, Answer ¶¶ 33, 43). Nine days later, on May 31, 2006, Barr filed a post-Answer motion to dismiss or in the alternative bifurcate and stay discovery on Plaintiffs' willful

infringement claim.<sup>1</sup> (D.I. 9). On June 9, 2006, Plaintiffs filed their Reply to Counterclaims. (D.I. 11).

### III. SUMMARY OF ARGUMENT

- 1. The circumstances at issue in *Glaxo* and *Allergan* were limited to the mere submission of an ANDA. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004); *Allergan, Inc. v. Alcon, Inc.*, C.A. No. 04-968 (GMS), 2005 WL 3971927 (D. Del. July 26, 2005) (Ex. 1). Barr's counterclaims expand this case beyond the mere submission of an ANDA. To the extent this Court does not limit that additional scope, Sanofi-Aventis' willful infringement claim is proper and should not be dismissed.
- 2. Even where only § 271(e)(2) acts of infringement are at issue, however, discovery concerning a willful infringement claim is appropriate in cases involving an ANDA filing with Paragraph IV certification. In fact, this Court has permitted such discovery even after Glaxo and Allergan. See SmithKline & French Labs., Ltd. v. Teva Pharma., USA, Inc., C.A. No. 05-197 (GMS), Hearing Tr. at 5, 8-9 (D. Del. July 28, 2005) (Ex. 2). Accordingly, Plaintiffs' willful infringement claims should not be dismissed at this early stage of litigation.
- 3. In seeking bifurcation under Rule 42(b), Barr bears the heavy burden of establishing that bifurcation will promote judicial economy and will not unduly prejudice either party. Smith v. Alyeska Pipeline Serv. Co., 538 F. Supp. 977, 982 (D. Del. 1982). Barr does not face a so-called "Quantum dilemma" absent bifurcation because the

3

Although Barr styled its motion as a Rule 12(b)(6) motion to dismiss, such a motion must be filed before any responsive pleading. Turbe v. Government of the Virgin Islands, 938 F.2d 427 (3d Cir. 1991); Elvig v. Calvin Presbyterian Church, 375 F.3d 951 (9th Cir. 2004). And, because the pleadings were not closed at the time Barr filed its motion, the motion should not be considered as a motion for judgment on the pleadings under Rule 12(c). Accordingly, it appears that Barr's motion should be treated as a Rule 12(h)(2) motion for failure to state a claim, in which event Barr's motion is premature, and not appropriate for resolution until the summary judgment stage.

Federal Circuit has disposed of any adverse inference flowing from a party's election not to produce an exculpatory opinion of counsel. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004) (*en banc*); *Trading Technologies, Int'l, Inc. v. Espeed, Inc.*, --- F. Supp. 2d ----, C.A. No. 04 C 5312, 2006 WL 1037322 (N.D. Ill. April 17, 2006) (Ex. 3). Because there is close overlap here between evidence of liability and willfulness, bifurcation would prejudice Sanofi-Aventis with the time and expense of presenting the same evidence twice. *Willemijn Houdstermaatchaapij BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1434-35 (D. Del. 1989). Accordingly, this Court should deny Barr's motion in the alternative to order bifurcation and stay discovery on willful infringement claims.

### IV. FACTUAL BACKGROUND

The claims of the patents-in-suit relate to aqueous nasal drug formulations that are useful in treating seasonal and allergic rhinitis ("patented formulations"). (D.I. 1, Ex. 1 at col. 1, 1. 5-18; D.I. 1, Ex. 2 at col. 1, 1. 13-26). The patented formulations contain the active ingredient triamcinolone acetonide ("TAA") (an anti-inflammatory steroid) and are administered to nasal mucosa via a non-aerosol metered-dose pump spray. (D.I. 1, Ex. 1 at col. 12, 1. 59-col.16, 1. 24; D.I. 1, Ex. 2 at col. 13, 1. 2-col.16, 1. 24). The patented formulations are sold under the trademark NASACORT AQ® pursuant to NDA 20-468. (D.I. 1, ¶ 10).

By letter dated March 20, 2006 ("certification letter"), Barr informed Sanofi-Aventis that Barr had submitted ANDA 78-104 seeking FDA approval to market a generic TAA aqueous nasal spray prior to expiration of the patents-in-suit. (Ex. 4). Barr's certification letter contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

("Paragraph IV certification") stating that in Barr's opinion the patents-in-suit were invalid, unenforceable or would not be infringed by Barr's proposed generic product. (Id. at p. 2 ¶ VI).

Barr's Paragraph IV certification mainly asserted

# REDACTED

#### V. ARGUMENT

- A. This Court Should Not Dismiss Sanofi-Aventis' Willful Infringement Claims, Especially if Barr's Declaratory Judgment Counterclaims Remain
  - 1. Willfulness Contentions Are Not Automatically Precluded in an ANDA Case, Particularly Where More Than Just a § 271(e)(2) Act of Infringement May Be At Issue

Barr is simply incorrect in asserting that "controlling Federal Circuit precedent" dictates dismissal of Sanofi-Aventis' willful infringement claim. (D.I. 10 ("Def. Br.") at p.1). Barr's arguments are based on the Federal Circuit's decision in *Glaxo* that merely filing an ANDA in good faith does not constitute willful infringement. (Def. Br. at 5-6). However, circumstances here are very different from those in *Glaxo*. Especially where, as here, the pleadings provide every indication that acts of infringement beyond §271(e)(2) may be at issue, *Glaxo* does not automatically preclude a claim of willful infringement.

In Glaxo, Apotex filed an ANDA seeking to market a generic version of the antibiotic drug product cefuroxime. Glaxo, 376 F.3d at 1343. Apotex's ANDA filing was "atypical" because cefuroxime was approved by the FDA under a provision of the Federal Food, Drug, and Cosmetic Act relating to antibiotics that did not require an ANDA applicant to submit one of the four types of certification under 21 U.S.C. § 355(j)(2)(A) that are usually required of manufacturers seeking to bring a generic drug to market. Id. at 1344. Accordingly, Apotex was not required to make and did not make a Paragraph IV certification that the patent at issue was invalid or was not infringed. Id.

The district court found that Apotex's ANDA submission infringed Glaxo's patent for cefuroxime and that such infringement was willful. *Id.* at 1345. The only

conduct supporting the district court's willfulness finding was Apotex's ANDA submission. The Federal Circuit agreed with Apotex that "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination . . . ." Id. at 1349 (emphasis added). In so holding, the Federal Circuit noted that "Apotex did not file a paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity," and that Apotex had not engaged in any litigation misconduct. Id. at 1351. Glaxo therefore does not preclude a determination of willfulness in this case, where acts of infringement appear to go beyond the mere submission of an ANDA, and paragraph IV certifications of invalidity may be baseless.

After Glaxo, this Court addressed a similar issue in Allergan, Inc. v. Alcon, Inc., C.A. No. 04-968 (GMS), 2005 WL 3971927 (D. Del. July 26, 2005). (Ex. 1). In Allergan, Alcon submitted an ANDA with Paragraph IV certification seeking to market a generic version of the ophthalmic drug product brimonidine tartrate. Id. at \*1. Allergan brought suit for infringement under § 271(e)(2), and further alleged that Alcon's infringement was willful because Alcon acted without a reasonable basis for believing that it would not be liable for infringement of the patents-in-suit. Id. By the time the case had proceeded to the summary judgment motion stage, Allergan had not produced sufficient facts beyond the mere submission of the ANDA and Paragraph IV certification that would support a claim for willful infringement. Id. at \*2. Accordingly, this Court dismissed Allergan's willful infringement claim. Id. Allergan does not preclude a determination of willfulness in this case because the acts of infringement at issue in Allergan did not, as here, go beyond a mere ANDA submission.

At bottom, neither the Federal Circuit nor this Court has held that a claim of willful infringement is never appropriate in an ANDA case. Indeed, in *SmithKline & French Labs.*, *Ltd. v. Teva Pharm.*, *USA*, *Inc.*, C.A. No. 05-197 (GMS), Hearing Tr. (D. Del. July 28, 2005) (Ex. 2) this Court has acknowledged that *Glaxo* does not hold that there can never be willful infringement in an ANDA filing situation:

Plaintiff's Counsel: ... The *Apotex* [sic: *Glaxo*] case does not hold there cannot be willful infringement from an ANDA filing.

The COURT: I agree.

(Id. at 5).

)

Here, Barr's counterclaims seek declarations of non-infringement based on actual manufacture, use, or sale of the products described in its ANDA (D.I. 6, ¶¶ 31, 41). Thus, Barr's Answer may seek to bring into play more than just § 271(e)(2) infringement. Because Barr's Answer provides every indication that more than just § 271(e)(2) infringement may be involved here, Plaintiffs' willful infringement claim is especially appropriate.

# 2. It Is Premature to Rule Out the Possibility That Discovery May Produce Evidence of Willful Infringement

Even where only § 271(e)(2) acts of infringement are at issue, however, discovery to support a willful infringement claim is appropriate. Indeed, this Court and others have permitted discovery in such circumstances to pursue a theory of willfulness premised on a frivolous and wholly unjustified ANDA filing with Paragraph IV certification. See SmithKline & French, Hearing Tr. at 8-9 (C.A. No. 05-197 (GMS)) (Ex. 2); see also Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., Civ. A. 05-CV-1887, 2005 WL 3664014, at \*2 (D.N.J. Dec. 30, 2005) (unpublished) (Ex. 7) (denying motion to strike

willfulness contention to provide patentee opportunity to show that additional activity beyond mere ANDA filing could support claim of willful infringement); *Eisai Co., Ltd. v. Dr. Reddy's Labs. Ltd.*, C.A. 03-9053, Hearing Tr. at 31-35 (S.D.N.Y. Oct. 12, 2004) (Ex. 8) (denying motion to strike willfulness contention and allowing discovery to determine if paragraph IV certification was subjectively baseless and unjustified).

In SmithKline, this Court held that it would be premature at the early pleadings stage of litigation to dismiss a claim of willful infringement premised on a baseless and wholly unjustified ANDA filing with paragraph IV certification:

Defendant's Counsel: ... We would say that there is no basis for willful infringement based on simply filing an ANDA....

The COURT: Wouldn't it be premature for the Court, though, at this point to rule out the possibility that discovery might adduce evidence that might support in some way a willfulness contention?

\* \* \*

Plaintiff's Counsel: I do believe it is premature, because, as I mentioned before, the filing of the ANDA, the *Apotex* [sic: *Glaxo*] case does not hold that that can't be the basis for willful infringement. Here the circumstances are very different. We have a Paragraph IV. The notice letter gives a very, very flimsy rationale for the basis for that. I think that alone can establish a prima facie case of willfulness.

We would then need to discover facts to further bolster that claim. But I think there is enough here to go forward....

The COURT: Okay. I am going to side with the plaintiff on this one at this stage, and suggest that this probably will, this issue may well be appropriate for summary consideration. . . .

(Ex. 2, at 6-8).

This Court's *SmithKline* ruling permitting discovery to pursue a willful infringement claim based on a theory that the ANDA filing was subjectively baseless came <u>after</u> its ruling in *Allergan* striking the willful infringement claim based on a similar

theory. The important distinction between the two cases is the then-current posture of litigation. In Allergan, by the time summary judgment motions were filed, the plaintiff had not produced sufficient facts in support of its willfulness contention. In SmithKline, the litigation was at a much earlier stage and the plaintiff had not yet had an opportunity to seek facts to support its willful infringement theories.

Here, the situation is exactly analogous to that of SmithKline. Because discovery has not yet opened, Sanofi-Aventis has not had an opportunity even to review Barr's ANDA submission, let alone seek to obtain facts to support its contention that Barr had no reasonable basis for its infringing actions.

#### REDACTED

- This Court Should Not Bifurcate and Stay Discovery On Plaintiffs' B. Willful Infringement Claims
  - 1. Defendants Would Not Be Severely Prejudiced By a Quantum Dilemma Because The Federal Circuit Now Holds That No Adverse Inference Flows From Failure to Produce an Opinion of Counsel

Bifurcation is "not to be routinely ordered." Lis v. Robert Packer Hosp., 579 F.2d 819, 824 (3d Cir. 1978). Bifurcation motions are granted "on a case-by-case basis" and only when the party seeking bifurcation can satisfy the burden of establishing that "separation will result in judicial economy and will not unduly prejudice any party." Smith v. Alyeska Pipeline Serv. Co., 538 F. Supp. 977, 982 (D. Del. 1982); see also Lis, 579 F.2d at 824. This presents a heavy burden for a party seeking bifurcation, as a "piecemeal trial on separate issues involved in one suit is not necessarily in the interest of swift, economical and nonprejudicial justice." Mellon v. Beecham Group PLC, 1991 WL 16494, 17 U.S.P.Q.2d (BNA) 1149, 1154 (D.N.J. 1989) (Ex. 9). Barr has not met and cannot meet that heavy burden in this case.

Barr argues incorrectly that it faces a so-called "Quantum dilemma" absent bifurcation. (Def. Br. at 8). In Quantum Corp. v. Tandon Corp., 940 F.2d 642 (Fed. Cir. 1991), the Federal Circuit discussed what used to be a Hobson's choice between the risk of "prejudicing [oneself] on the question of liability" by disclosing an opinion of counsel, and the risk of "being found to be a willful infringer" by not disclosing the opinion. Quantum, 940 F.2d at 644. At the time Quantum was decided, a withholding of an opinion of counsel led to an adverse inference that "either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue its use of the patentee's invention." Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568, 1572-73 (Fed. Cir. 1988), overruled by Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337 (Fed. Cir. 2004) (en banc). However, the Federal Circuit disposed of the adverse inference in Knorr-Bremse Systeme

In *Knorr-Bremse*, the Federal Circuit held that "no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel." 383 F.3d at 1341.

Elimination of the adverse inference in *Knorr-Bremse* alleviates the so-called *Quantum* dilemma. Thus, although a defendant still may face a difficult tactical decision in terms of whether to waive its attorney-client privilege in defending against a willful infringement claim, absent the adverse inference a defendant is only slightly prejudiced, and bifurcation is not appropriate on that basis. *Trading Technologies, Int'l. Inc. v. Espeed, Inc.*, — F.Supp.2d —, C.A. No. 04 C 5312, 2006 WL 1037322, at \*4 (N.D. III. April 17, 2006). (Ex. 3).

# 2. Bifurcation Would Be Judicially Inefficient and Would Prejudice Plaintiffs With The Need to Present Some Evidence Twice

Courts often deny bifurcation of willfulness claims, especially where they are not coupled with damages claims. Kos Pharm., Inc. v. Barr Labs., Inc., 218 F.R.D. 387, 390-91 (S.D.N.Y. 2003). "[T]rial practicalities and the weight of authority tilt the application of Rule 42(b) against separation of willfulness from liability absent a basis for bifurcation justified by damages claims." Id. at 392; see also Calmar, Inc. v. Emson Research, Inc., 850 F. Supp 861 (C.D. Cal. 1994). Efficiency considerations in a case without complex damages issues clearly favor one trial. Johns Hopkins Univ. v. Cellpro, 160 F.R.D. 30 (D. Del. 1995).

There is certainly no basis for Barr's assertion that "bifurcation is appropriate because there will be little overlap between the liability and willfulness issues." (Def. Br. at 10). Bifurcation would be particularly inefficient in this case because of the significant overlap between the issues of validity and willfulness. See, e.g., Real v. Bunn-O-Matic Corp., 195 F.R.D. 618, 626 (N.D. III. 2000) ("[W]illfulness cannot be easily partitioned into a separate issue to be decided in a vacuum."). Bifurcation promotes judicial

economy only if the second trial never takes place. The insubstantial nature of Barr's invalidity assertions is strong evidence that those assertions have not been made in good faith and that Barr's infringement is willful. There is a close overlap in proofs for showing patent validity and the ultimate willfulness conclusion that Barr's invalidity arguments lack any substantial support and were not advanced in good faith. *Kimberly-Clark Corp. v. James River Corp.*, 131 F.R.D. 607, 609 (N.D. Ga. 1989) ("[T]he defendant's state of mind when it infringed the patent [is] a finding of fact inextricably bound to the facts underlying the alleged infringement."). If a second trial turns out to be required, bifurcation introduces "considerable delay," *Real*, 195 F.R.D. at 620, and requires the presentation of much of the same evidence twice. *Willemijn Houdstermaatschaapij BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1434-35 (D. Del. 1989).

If willfulness were bifurcated from liability, Sanofi-Aventis would be prejudiced by the inefficiency of the time and expense of presenting much of the same evidence twice.

### REDACTED

Plaintiffs should not be required to present this same evidence twice in two different

trials. See Willemijn, 707 F. Supp. at 1434 (rejecting bifurcation where "it is obvious that separate trials in the present case would require plaintiff to present at least a limited amount of evidence twice . . . .").

In sum, this Court should deny Barr's request for bifurcation and a discovery stay on willful infringement claims, because lack of bifurcation does not severely prejudice Barr, and bifurcation would prejudice Sanofi-Aventis and present judicial inefficiency.

#### VI. CONCLUSION

Plaintiffs respectfully request that this Court deny Defendant's motion to dismiss or in the alternative bifurcate and stay discovery on willful infringement claims, to avoid prejudicing Plaintiffs and to avoid judicial inefficiency.

#### **ASHBY & GEDDES**

/s/ John G. Day

Steven J. Balick (I.D.#2403)
John G. Day (I.D. #2114)
Tiffany Geyer Lydon (I.D. #3950)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
302-654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tlydon@ashby-geddes.com

Attorneys for Plaintiffs

# Of Counsel:

Paul H. Berghoff
Joshua R. Rich
Jeremy E. Noe
Paul S. Tully, PhD
McDONNELL BOEHNEN
HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, Illinois 60606
(312) 913-0001

Dated: June 21, 2006

170649.1

# **CERTIFICATE OF SERVICE**

I hereby certify that on the 28<sup>th</sup> day of June, 2006, the attached REDACTED PUBLIC VERSION OF PLAINTIFFS' ANSWERING BRIEF OPPOSING BARR'S MOTION TO DISMISS OR BIFURCATE AND STAY DISCOVERY ON WILLFUL INFRINGEMENT CLAIM was served upon the below-named counsel of record at the address and in the manner indicated:

Josy W. Ingersoll, Esquire Young Conaway Stargatt & Taylor, LLP The Brandywine Building 1000 West Street, 17<sup>th</sup> Floor Wilmington, DE 19801

HAND DELIVERY

George C. Lombardi, Esquire Winston & Strawn LLP 35 West Wacker Drive Chicago, IL 60601-9703

VIA FEDERAL EXPRESS

/s/ John G. Day

John G. Day

169789.1

# EXHIBIT 1

# Westlaw.

Slip Copy

Slip Copy, 2005 WL 3971927 (D.Del.)

(Cite as: Slip Copy)

Page 1

### H

Briefs and Other Related Documents

Only the Westlaw citation is currently available.
United States District Court, D. Delaware,
ALLERGAN, INC., and Allergan Sales, LLC,
Plaintiffs,

V.

ALCON INC., Alcon Laboratories, Inc., and Alcon Research, Ltd., Defendants. Civil Action No. 04-968 (GMS).

July 26, 2005.

William J. Marsden, Jr., Sean Paul Hayes, Fish & Richardson, P.C., Wilmington, DE, for Plaintiffs.

Josy W. Ingersoll, Karen Elizabeth Keiler, Young, Conaway, Stargatt & Taylor, Wilmington, DE, for Defendants.

#### ORDER

GREGORY M. SLEET, District Judge.

\*1 1. Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan") filed the above-captioned action against Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, "Alcon") on August 24, 2004. Allergan filed this suit for patent infringement pursuant to 35 U.S.C. § 271(e)(2). [N1] The complaint alleges that Alcon infringes U.S. Patent No. 6,673,337 (the " 337 patent") and U.S. Patent No. 6.641,834 (the "834 patent") because it submitted a § 505(b)(2) application, or paper New Drug Application ("paper NDA"), to the Food and Drug Administration ("FDA"), seeking approval of its proposed generic brimonidine tartrate ophthalmic drug product. FN2 (Compl.¶ ¶ 14-15, 17.) The complaint further alleges that Alcon acted without a reasonable basis for believing that it would not be liable for infringement of the 337 and 834 patents and, as such, its infringement of the 337 and 834 patents is willful. (Id. ¶ ¶ 19, 23.) Allergan requests injunctive relief and attorney's fees, pursuant to 35 U.S.C. & 285. FNJ The issue presently before the court is whether Allergan may assert a claim for willful infringement.

FN1. Section 271(e)(2) states, in pertinent part:

(i)t shall be an act of infringement to submitan application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. 35 U.S.C. § 271(e)(2)(A).

FN2. Alcon also filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4), or Paragraph IV Certification, alleging that the 337 and 834 patents are invalid and/or not infringed by its product.

FN3. Section 285 provides: "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." The Federal Circuit has recognized willful infringement as a type of misconduct that creates an exceptional case. See Hofmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1365 (Fed.Cir.2000) (citing Beckman Instruments, Inc. v. LKB Produkter AB, 894 F.2d 1547, 1151 (Fed.Cir.1989)).

- 2. Allergan contends that a willfulness claim is proper based on the totality of the circumstances. Allergan further contends that the totality of the circumstances comprises many factors, including whether Alcon intentionally copied ALPHAGAN® P. whether Alcon exercised due care to avoid infringing Allergan's patents, whether Alcon relied on competent legal advice, and Alcon's behavior as a party to the litigation. (D.I. 64, at 2.) According to Allergan, its claim of willfulness is based the following: (1) Alcon's Paragraph IV certification was filed without reasonable basis; and (2) Alcon's conduct in the litigation demonstrates its lack of reasonable basis. (Id. at 3). Lastly, Allergan contends that the Federal Circuit's holding in Glaxo Group Ltd. r. Apotex. Inc., 376 F.3d 1339 (Fed.Cir.2004) does not foreclose a claim for willful infringement in Abbreviated New Drug Application ("ANDA") or paper NDA cases. (Id.)
- 3. Alcon asserts that the only act of infringement

Slip Copy

Slip Copy, 2005 WL 3971927 (D.Del.) (Cite as: Slip Copy)

Case 1:06-cv-00286-GMS

alleged in the complaint is the filing of its paper NDA with the FDA. According to Alcon, in light of the Federal Circuit's holding in Glaxo, "Allergan's conclusory allegation-standing alone-cannot support a charge of willful infringement." (D.I. 75, at 2.)

The Federal Circuit first addressed the issue of willfulness in ANDA and paper NDA cases in Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir2000), In Yamanouchi, the court found that "[a]n ANDA [or paper NDA] filing by its very nature is a highly artificial act of infringement,' therefore, the trial court need not have elevated the ANDA certification into a finding of willful infringement." 231 F.3d at 1347. Nonetheless, the court held that the case was exceptional and awarded attorney fees to the plaintiff, based on the defendant's "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed...." Id.

- \*2 The Federal Circuit addressed the issue again in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed.Cir.2004), holding that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." 376 F.3d at 1350-51. In the Glaxo opinion, the court explained that in Yamanouchi it "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." Id. at 1350. According to the court, "in Yamanouchi we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification." Id.
- 6. In the present case, Allergan has not pointed to anything which would support a finding of willful infringement. The only act of infringement alleged in Allergan's complaint is Alcon's allegedly baseless paper NDA filing and Paragraph IV Certification with the FDA. Because a paper NDA filing cannot be considered willful, Allergan's complaint does not state any basis under which it could assert a claim for willful infringement. Allergan, however, maintains that Alcon's change in position with respect to its written description defense set forth in its summary judgment motion, combined with the paper NDA filing, permits a claim for willful infringement. The

court disagrees. As the Federal Circuit explained in Glaxo, a finding that a ANDA/paper NDA case is "exceptional" can be based on meritless filings combined with litigation misconduct, but a finding of willful infringement cannot. Accordingly, the court will not permit a claim for willful infringement in this case. That being said, the court will not foreclose Allergan from, at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case for which the court should award attorney's fees. See Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc., 355 F.Supp.2d 586, 592-93 (D.Mass.2005).

#### Therefore, IT IS HEREBY ORDERED that:

- 1. A claim for willful infringement is not permitted in this case.
- 2. Allergan's claim for willful infringement shall be stricken from the complaint.

D.Del., 2005. Allergan, Inc. v. Alcon, Inc. Slip Copy, 2005 WL 3971927 (D.Del.)

Briefs and Other Related Documents (Back to top)

- · 2006 WL 809119 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Opposition to Defendants' Motion for Reargument or Reconsideration of its Motion for Leave to Amend its Answer (Feb. 15, 2006) Original Image of this Document (PDF)
- 2005 WL 2603655 (Trial Motion, Memorandum) and Affidavit) Plaintiffs' Reply Brief in Support of Plaintiffs' Provisional Motion to Amend the Scheduling Order (Sep. 2, 2005) Original Image of this Document (PDF)
- 1:04cv00968 (Docket) (Aug. 24, 2004)

END OF DOCUMENT

# EXHIBIT 2

		<del> </del>
	1	3  THE COURT: Why so long?
1. IN THE CHARLES STATES PARTY.		
2 YA AND THE THE STREET OF	Official Company	- A STATE OF
3		need a year to complete the discovery. We believe in tide
4 SHOOM EXPER & PRODUCE 3	Civil Rattan	case the burden of fact discovery is going to fall
S MOTORING EXCEPTS and	1	g qishroportionately on our side pecause of the time periods
COMPONENTIAN d/b/e CANCENDETERATION,		I involved. The two patents at issue to the case are from
Flaintiffe,	j	7 1984 and 1989, respectively. That is quite a long time
· * ;	ì	period that her elapsed. There has been no indication from
TEM PRESENTATION, DR., 1		defendants that they are willing to limit the scape or the
De Complant, 1	No. 65-197-G/9	· · · · · · · · · · · · · · · · · · ·
11 Silington, Poles etc., 1995		
27 9:00 min.		The state of the s
In Charlesce	1	- Carrier Language and Architecture College of 1948
14 SERVER: PERSONNEL GROUNT H. MART, U.	5,2,C,C,	International side to this case, as one of the patents was
15 APPERUNDES:	· •	the result of work that was performed in England.
14 MATRICEL MENT BOCKER, EDG. Commelly Both Lodge & Roth LLD	1	So there are many witnesses who may not be
17 , and , organ a next law , and E. W. All E. Wieseler, tag.	1	simployees who are located outside the country, documents
14 Milmer, Cotier, Pirkering, tel. (Kiekington, C.C.)	a and Dairs till	•
19 Cotravel for	statustes 1	In addition, we think that the scope of the
. 24 Richard V. Mahada ben.	· ·	
71 Formig Combray Starquets 5 Taylor		No. of the control of
22 ARY D. LEXAMORE, INC., and PARAM REPUBLIE, LIQ. 23 Michigal & Mile Else	2	_
Mar Tank, New York		
24	`   _	and the second of the second s
IS Columnial for t		
	24	MS. WXSMORE: There has been a paragraph for
1 YHE COUNTY Which side to plaint 2 MS. WIGMORE: Here. I am	. 1	THE COURT: I understand that.  MS. WIGNORE: Obviously, they are aware of our
3 Wilmer, Cutier, Pickering, Hale and Dor:		patents. The rational and the paragraph for notice is very
4 MS. ROGOWSKI Good morn		Hasted for timer argument of invalidity and
5 MR. MORSE: Your Honor, go		•
6 Robinson and Jay Lafkowitz.	on sections. Patest	noniniringament.
A 11-1-11-11-11-11-11-11-11-11-11-11-11-1		THE COURT: What is the rationale for
7 THE COURTY Good morning.	· · · · · · · · · · · · · · · · · · ·	plaintiffs' contentions that there is willful infringement
8 MR. LEFKOWITZ: Good mort	ang, Your Honor,	,
	٠ .	in light of the cases?
9 MS, ROBINSON: Good moral	ing.	,
		in light of the cases?  MS. WIGHORE: First of all, our case is
9 MS, ROBINSON: Good morni	Mr. Luc's name? ((	in light of the cases?  MS. WIGMORE: First of all, our case is  distinguishable from the Apotex case.
9 MS, ROBINSON: Good moral 10 THE COURT: Okay, Did I see	o Mr. Lee's name? ((	in light of the cases?  MS. WIGHORE: First of all, our case is  distinguishable from the Apotex case.  THE COURT: Merely because of Faragraph 47
9 MS, ROBINSON: Good moral 10 THE COURT: Chay, Did I see 11 MS, WIGNORE: He is on tria	o Mr. Lue's name? (Control of the moreont. 11 in this case? 12	in light of the cases?  MS. WIGMORE: First of all, our case is  distinguishable from the Apotax case.  THE COURT: Merely because of Faragraph 47  MS. WIGMORE: That is one reason. Also, in the
9 MS, ROBINSON: Good moral 10 THE COURT: Okay, Did 1 sec 11 MS, WIGNORE: He is on trial 12 THE COURT: Will he be lead	o Mr. Lue's name? (Constitution of the moreont. (Constitution of the constitution of t	in light of the cases?  MS. WIGHORIS Pirst of all, our case is  distinguishable from the Apotox case.  THE COURT: Merely because of Paragraph 47  MS. WIGHORIS That is one reason. Also, in the  Apotox case, it is very clear, although in that case it is
9 MS, ROBINSON: Good moral 10 THE COURT: Okay, Did X sec 11 MS, WIGMORE: He is on trie 12 THE COURT: Will he be lead 13 MS, WIGMORE: Yes, he will, 14 THE COURT: Okay, I have lo	e Mr. Lue's name? 10 I et the moreant. 11 in this case? 12 insided at your joint. 14	in light of the cases?  MS. WIGMORE: First of all, our case is  distinguishable from the Apotex case.  THE COURT: Merely because of Faragraph 47  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but
9 MS, ROBINSON: Good moral 10 THE COURT: Okay. Did I see 11 MS, WIGNORE: He is on tria 12 THE COURT: Will he be lead 13 MS, WIGNORE: Yes, he will, 14 THE COURT: Okay. I have in 15 status report, preparing it. There are so	o Mr. Lue's name?  I st the moreant.  In this case?  13  soked at your joint  14  15  16  17  18  18  18  18  18  18  18  18  18	in light of the cases?  MS. WIGMORE: First of all, our case is  distinguishable from the Apotex case.  THE COURT: Merely because of Faragraph 47  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary
9 MS, ROBINSON: Good moral 10 THE COURT: Okay. Did I see 11 MS, WIGNORE: He is on tria 12 THE COURT: Will he be lead 13 MS, WIGNORE: Yea, he will, 14 THE COURT: Okay. I have le 15 status report, preparing it. There are so 16 attomp you, or between you, as to at lea	o Mr. Lee's name?  I st the moment.  In this case?  It this case?	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  THE COURT: Merely because of Furagraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.
9 MS, ROBINSON: Good moral 10 THE COURT: Okay. Did I see 11 MS, WIGNORE: He is on trial 12 THE COURT: Will he be lead 13 MS, WIGNORE: Yea, he will. 14 THE COURT: Okay. I have id 15 status report, preparing it. There are so 16 among you, or between you, as to at lead 17 be done, and perhaps what should be do	o Mr. Lee's name?  I st the moment.  In this case?  It is the case case case case case case case cas	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotax case.  THE COURT: Merely because of Paragraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotax case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary chromosomers present.  THE COURT: What might those extraordinary
9 MS. ROBINSON: Good moral 10 THE COURT: Okay. Did 3 sec 11 MS. WIGNORE: He is on trial 12 THE COURT: Will he be lead 13 MS. WIGNORE: Yea, he will. 14 THE COURT: Okay. I have lo 15 status report, preparing it. There are so 16 among you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of leases, or at leaset willfulness.	o Mr. Lee's name?  I st the moment.  In this case?  It is the case?  It is case?  I	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  THE COURT: Merely because of Faragraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.  THE COURT: What might those extraordinary circumstances be in an ANDA situation?
9 MS. ROBINSON: Good moral 10 THE COURT: Okey. Did I see 11 MS. WIGMORE: He is on trial 12 THE COURT: Will he be lead 13 MS. WIGMORE: Yes, he will. 14 THE COURT: Okey. I have le 15 status report, preparing it. There are so 16 stoom you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of leaves, or at least willfulness, 19 bone of contention.	o Mr. Lee's name?  I st the moveent.  In this case?  It is in this case?  It is in this case?  It is in this case?  It think, is a  It think, is a	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  THE COURT: Merely because of Faragraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.  THE COURT: What might those extraordinary circumstances be in an ANDA situation?
9 MS. ROBINSON: Good moral 10 THE COURT: Okay. Did 3 sec 11 MS. WIGMORE: He is on trial 12 THE COURT: Will he be lead 13 MS. WIGMORE: Yea, he will. 14 THE COURT: Okay. I have lo 15 status report, preparing it. There are so 16 second you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of leaves, or at leaset willfulness.	o Mr. Lee's name?  I st the moveent.  In this case?  It is in this case?  It is in this case?  It is in this case?  It think, is a  It think, is a	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  THE COURT: Merely because of Faragraph 47  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.  THE COURT: What might those extraordinary circumstances be in an ANDA situation?  MS. WIGHORE: The circumstances may be basic.
9 MS. ROBINSON: Good moral 10 THE COURT: Okay. Did I see 11 MS. WIGNORE: He is on trial 12 THE COURT: Will he be lead 13 MS. WIGNORE: Yes, he will. 14 THE COURT: Okay. I have le 15 status report, preparing it. There are so 16 attorn you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of leaves, or at least willfulness, 19 bone of contention.	t Mr. Lue's name?  I st the moment.  In this case?  It is the moment.  It this case?  It is the moment.  It is the moment.  It is case?  It is case?	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  The Court: Merely because of Paragraph 47  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.  THE COURT: What inight those extraordinary circumstances be in an ANDA situation?  MS. WIGHORE: The circumstances may be basical frivolous argument for invalidity or moninfringement.
9 MS, ROBINSON: Good moral 10 THE COURT: Okay. Did I see 11 MS, WIGNORE: He is on tria 12 THE COURT: Will he be lead 13 MS, WIGNORE: Yes, he will, 14 THE COURT: Okay. I have ic 15 status report, preparing it. There are so 16 among you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of leases, or at least willfulness, 19 bone of contention. 20 What I would like to start ou	the Mr. Lue's name?  I st the moment.  In this case?  It in this case?  It is the moment.  It is the moment in the moment in the moment is the moment in the mo	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  THE COURT: Merely because of Paragraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.  THE COURT: What might those extraordinary circumstances be in an ANDA situation?  MS. WIGMORE: The circumstances may be basice a frivolous argument for invalidity or nonlatingement.
9 MS, ROBINSON: Good morns 10 THE COURT: Okay. Did I see 11 MS, WIGNORE: He is on tria 12 THE COURT: Will he be lead 13 MS, WIGNORE: Yes, he will, 14 THE COURT: Okay. I have ic 15 status report, preparing it. There are so 16 among you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of issues, or at least withtuness, 19 bone of contention. 20 What I would like to start ou 1 the difference in the proposed timelines	o Mr. Lee's name?  I st the moment.  In this case?  It in this case	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  THE COURT: Merely because of Paragraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very char, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary circumstances present.  THE COURT: What might those extraordinary circumstances be in an ANDA cituation?  MS. WIGHORE: The circumstances may be basic; a frivolous argument for invalidity or nonlatingement.  THE COURT: Wouldn't that go to exceptional case rather than whether or not there has been willful
9 MS. ROBINSON: Good moral 10 THE COURT: Okay. Did I see 11 MS. WIGNORE: He is on trie 12 THE COURT: Will he be lead 13 MS. WIGNORE: Yes, he will. 14 THE COURT: Okay. I have ic 15 status report, preparing it. There are se 16 among you, or between you, as to at lea 17 be done, and perhaps what should be do 18 couple of issues, or at least willfulness, 19 bone of contention. 20 What I would like to start ou 1 the difference in the proposed timelines 2 discovery. Plaintik is at just about a yes	o Mr. Lee's name?  I st the moment.  In this case?  It in this case	in light of the cases?  MS. WIGMORE: First of all, our case is distinguishable from the Apotex case.  The COURT: Merely because of Paragraph 4?  MS. WIGMORE: That is one reason. Also, in the Apotex case, it is very clear, although in that case it is not automatic that there would be willful infringement, but it is certainly possible if there are extraordinary chromateness present.  THE COURT: What might those extraordinary chromateness be in an ANDA cituation?  MS. WIGHORE: The circumstances may be basic; a frivolous argument for invalidity or moninfringement.  THE COURT: Wouldn't that go to exceptional case rather than whether or not there has been willful infringement, an exceptional case determination?

1	your patents are simply invalid because they are cobbling
2	together two pieces of prior art that we believe in no way
3	indicates invalidity, I think that is that could go to
4	willfulness.
5	THE COURT: But thinking about what infringement
6	is, making, using, saling, are we really talking about
7	infringement or are we talking about attorney misconduct for
8	which they should be punished?
9	MS. WIGHORE: I believe we are talking about
10	infringement. The Apotex case does not hold there cannot be
11	willful intringement from an ANDA Hilling.
12	THE COURT: Fagree.
13	MS. WIGNORE: On those facts, the Court forms
14	there could not be. If one files a Paragraph 4
15	curtification, the statute is dear that that can constitute
16	infringement. If that is done with insufficient rationale,
17	where it's known that the patents exist, and that the
18	argument put together to support the notice is frivolous, we
19	believe that would constitute willful infringement.
20	THE COURT: Why doesn't a Paragraph 4 filing
21	make this —
22	MS. ROBINSON: Your Horse, I think Apotes and,
23	quite honestly, a recent decision, Apotex and a recent order
24	from Your Honor makes clear
25	THE COURT: Two days ago,
_	
1	MS, ROBINSOR: Yes, makes clear that the
•	Wadami

whether or not the case is exceptioned. 2 THE COURT: Wouldn't it be premature for the Court, though, at this point to rule out the possibility that discovery might address evidence that might support in some way a willfulness contention? MS. ROBINSON: We don't believe so, Your Honor. At the moment, the best that you are going to find out is the most that discovery could disclose is whether or not there was a reasonable basis for the assertions made in our 10 ANDA Paragraph 4 curtification. 11 That alone wouldn't give rice to a finding of 12 williubass. So If you include it now, it certainly would assist in narrowing the issues. 14 THE COURT: Sure would. 15 MS. ROSYNSON: It would marrow the scope of discovery. To the extent that plaintiffs' discovery .17 timeline includes time to do discovery on willful infringement, that certainly would cut down on the time that 18 19 plaintiffs contend they need. 20 THE COURT: What is your response to that lest 21 question? 22 MS. WIRMORE: On that point I don't believe there would be a significant difference in time period — 23 24 THE COURT: But answer my last question. I 25 might agree with you on that. The question I posed to 1

2 Federal Circuit does not believe that a more paper tiling. 3 simply filing an ANDA, constitutes infringement, could constitute willful infringement. It is technical infringement in order to get the ball started for purposes of Irligation. But there is so making, there is no offering 7 for sale. R Quite honestly, we think that Apotex makes clear

that the only avenue that is still available is absent some actual damages. That is a separate leage. The 30-month stay which runs as we extually started manufacturing the product, that is a different issue.

In the elsence of anything other than simply filling an ANDA, if there is some type of misconduct with respect to whether or not you have a good-faith basis for making the argument, that would put it into the exceptional

18 In our opinion, that is no different then a Rule 19 11 type consideration.

20 We would say that there is no basis for willful 21 AUMA ne gnilit yiqnia ne beest tnemegalini

22 Discovery misconduct again would go towards — I think that is what the Apotex case really bung its hat on, 23 24 discovery misconduct might be something that the Court can consider. But again, that would be to the context of

2

3

5

11

12

13

14

20

21

22

23

MS. WIGHORE: I am sorry. Which question? THE COURT: Now I have to remember it. As to whether it was preparture.

MS. WISHORE: I do believe it is premature, because, as I mentioned before, the filing of the ANDA, the Apotex case does not hold that that can't be the basis for willful infringement. Here the circumstances are very Afficient. We have a Paragraph 4. The notice letter gives a very, very flinsy rationale for the basis for that. I think that alone can establish a printa facie case of willfulnee

We would then need to discover facts to further bolster that claim. But I think there is enough here to go forward. Just us plaintiffe here are purating on infringement defense and, from our side, we think it's quite clear that there is infringement, I think the situations are very parallel. And if they are able to pursue that dains, then willful infringement should cartainly be comething that we should be able to pursue.

THE COURT: Okey.

I am going to side with the plaintiff on this one at this stage, and suggest that this probably will, this 24 issue may well be appropriate for summary consideration. Whether or not I grant permission to file other motions for

10

11

12

13

15

16

47

•

```
summary judgment, it is likely that there will come time for
                                                                                1
                                                                                                THE COURTS Four said a half months between fact.
   2
       us to angage that process. There are not going to be
                                                                                7
                                                                                    and expire 12
       material facts in dispute. We will probably be able to take
                                                                                3
                                                                                                MS, ROBINSON: Right. The completion of fact
       a look at it on summary judgment, at least help parrow the
                                                                                4
                                                                                    discovery would be July 28th, under plaintiffs' schedule.
       field for trial, if not for discovery.
                                                                                    and the completion of expert discovery is not until Hovember
   6
                  MS. ROBINSON: Your Hotter, on that issue, we
                                                                                    30th. I guess that's four months. That's more time than we
   7
       might suggest that this particular issue is particularly
                                                                                    think is really necessary. We curtainly can test that,
       amenable to entiter motions, dispositive motions.
                                                                                                THE COURGY I think what is going to drive this,
                  THE COURT: Except I am not poing to give you
                                                                                9
                                                                                    he well as times considerations, the considerations of what.
       mure than one round. I might otherwise agree with you.
 10
                                                                              10
                                                                                    is accessary, what is going to be necessary in terms of
 11
                  I am still not convinced that you need a year
                                                                                    time, I too am convinced that the parties will likely work
 12
       for discovery in this case. You got to do a better job,
                                                                                    out matters such as with regard to inventors and people of
 13
       comusel, to convince me then you have done so far. I
                                                                                    that nature so that you won't have to go through the Hagne
 14
       understand you indicate that there are foreign entities
                                                                              44
                                                                                    Convention. I just not that long ago had 65% in front of
 15
       involved. Where?
                                                                                   mit, I think there ware England Issues, because there always
 46
                  MS. WIGKOKE: In England,
                                                                              16
                                                                                   ern with GlassSmithRise, And there was no difficulty in
 17
                  THE COURT: England.
                                                                              17
                                                                                   tide regard,
 18
                  MS. WIGNORE: There may be witnesses who have
                                                                              18
                                                                                               So I are not going to factor that into my
 19
      moved to other countries. But England is the primary area.
                                                                              19
                                                                                   calculus is determining an appropriate amount of their for
 20
                  THE COURT: Are there any conventions that are
                                                                              26
                                                                                   fact discovery.
 21
      going to have to be utilized?
                                                                              21
                                                                                               Are there other resume, counsel, that you think
22
                  MS. WIGHORE: I believe the Hagne Convention may
                                                                              22
                                                                                   an entire year --- let me share with you, also, I am really
23
      have to be utilized because of the former employees and
                                                                                   distinctioned to have this case come to trial as late as '07.
      perhaps other parties involved. We are still investigating
                                                                                   This case was filed a little more than three months ago. I
25
      that. That is certainly a possibility.
                                                                                   do disagree, based on the little bit that I admittedly have
                                                                                                                                          19
  1
                 THE COURT: What is your view?
                                                                                   in front of me, but I don't understand why this case would
  2
                 MS. ROBENSON: Your Honor, If we are talking
                                                                                   be assurately characterized as more complex time any other
      discovery in London, I understand that one of the inventors
  3
                                                                                   patent case that we have. Patent cases by definition are
      on one of the patents at the time the patent based was a
                                                                                   complex civil litigation.
      British citizen, employee of GSK. You know, our position on
                                                                              5
                                                                                              Wity for this a complex patent case.
      that is, we are more than happy to travel to London. It's
                                                                              6
                                                                                              MS. WIGHORS: Your Honor, I think the issue is
      really no more difficult going to London than it is to go to
                                                                                   not so much complexity as scope. Perhaps there are ways for
     California. And we are hopeful that we could work with
                                                                                  the parties to work together to narrow the scope concentrat.
     plaintiff so we wouldn't have to go through the Hague
                                                                                   One of the big concerns we have is there frame, because the
10
     Convention. This is, as I understand from pinintitis'
                                                                             40
                                                                                  palants, the applications go back to 1982. We have got no
11
     counsel, a former employee. We would hope that we wouldn't
                                                                                  indication as of the present time that there will be any
     have to go through these entraordinary steps to get
12
                                                                             12
                                                                                  time limitation on what is being sought in discovery.
43
     potentially an inventor to give testimony during this case.
                                                                             13
                                                                                             THE COURT: You are concerned about walkity.
                I just don't tidak that, we don't believe that
14
                                                                             14
                                                                                  the scope of validity?
15
     this type of discovery, this type of international discovery
                                                                             15
                                                                                             M5. WIGHORE: Very much so. We have a very
16
     that's being discussed by pleintiff really is the type of
                                                                             16
                                                                                  large corporation that has gone through multiple corporate
17
     discovery that requires extraordinary amounts of time to get
                                                                             17
                                                                                  changes, multiple employees who have come and goes. We are
18
     through discovery.
                                                                             18
                                                                                  very concerned about being able to gather that volume of
19
                One of the other issues, I would point out. Your
                                                                             19
                                                                                  documents, particularly if we are going up to the present
20
     Honor, is that there is four and a half months between the
                                                                           .20
                                                                                  time and if they are going to be asking for current
    close of fact discovery and the close of expert discovery in
                                                                                  marketing documents and things of that nature. It is a very
                                                                            21
    plaintiffs' schedule. To the extent that hades up a
                                                                            22
                                                                                 large burden. We want to make sure that we can get than
     large portion of the time frame that we are talking about.
                                                                            23
                                                                                  what they are asking for in the time allotted.
    we just think that that is probably more time than is really
                                                                            24
                                                                                             THE COURT: The point that coursel makes is a
    required or necessary.
                                                                                  worthy one. It causes me to say this. I don't want to have
```

# EXHIBIT 3

# Westlaw.

--- F.Supp.2d ----, 2006 WL 1037322 (N.D.III.) (Cite as: --- F.Supp.2d ----)

Page 1

#### Н

Briefs and Other Related Documents

Only the Westlaw citation is currently available.
United States District Court, N.D. Illinois, Eastern
Division.

TRADING TECHNOLOGIES INTERNATIONAL, INC., Plaintiff,

v. ESPEED, INC., et al., Defendants. No. 04 C 5312,

April 17, 2006.

Background: Patentee sued alleged infringers for patent infringement, including willful infringement. Alleged infringers moved to bifurcate trial and discovery.

Holdings: The District Court, Moran, Senior District Judge, held that:

9(1) alleged infringers were only slightly prejudiced as a result of choice, absent bifurcation, between asserting advice-of-counsel defense to willful infringement claim and maintaining attorney-client privilege;

11(2) alleged infringers did not establish that bifurcation of discovery and trial would promote judicial efficiency;

12(3) bifurcation of trial would prejudice patentee; and

15(4) bifurcation was not warranted.

Motion denied.

# [1] Federal Civil Procedure 170A 1955

170A Federal Civil Procedure

170AXV Trial

170AXV(A) In General

170Ak1954 Separate Trials in Same Action

170Ak1955 k. Grounds and Objections.

Most Cited Cases

Under three-step process for determining whether to bifurcate trial, court must first determine whether separate trials would avoid prejudice to a party or promote judicial economy, then must be satisfied that decision to bifurcate does not unfairly prejudice non-moving party, and, finally, must not grant separate trial if doing so would violate the Seventh Amendment. U.S.C.A. Const. Amend. 7; Fed. Rules Civ. Proc. Rule 42(b), 28 U.S.C.A.

#### [2] Federal Civil Procedure 170A 2 1954.I

170A Federal Civil Procedure 170AXV Trial

170AXV(A) In General
170Ak1954 Separate Trials in Same Action
170Ak1954.1 k. In General. Most Cited

Cases

Although ultimate decision to bifurcate trial is within district court's discretion, because court is expected to act to secure the just, speedy, and inexpensive determination of every action, bifurcation remains the exception, not the rule. Fed.Rules Civ.Proc.Rules 1, 42(b), 28 U.S.C.A.

# [3] Patents 291 5 314(2)

291 Patents

291XII Infringement 291XII(C) Suits in Equity

291k314 Hearing

291k314(2) k. Scope of Inquiry and

Power of Court. Most Cited Cases

Patent cases are no exception to the rule that bifurcation of trial is the exception, not the rule. Fed.Rules Civ.Proc.Rules 1, 42(b), 28 U.S.C.A.

#### [4] Federal Civil Procedure 170A 1955

170A Federal Civil Procedure

170AXV Trial

170AXV(A) In General

170Ak1954 Separate Trials in Same Action 170Ak1955 k, Grounds and Objections.

Most Cited Cases

Party seeking separate trials has the burden of showing that judicial economy would be served and that the balance of potential prejudice weighs in favor of bifurcation. Fed.Rules Civ.Proc.Rule 42(b), 28 U.S.C.A.

151 Patents 291 312(8)

-- F.Supp.2d ---, 2006 WL 1037322 (N.D.III.)

(Cite as: --- F.Supp.2d ----)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k312 Evidence

291k312(3) Weight and Sufficiency 291k312(8) k. Participation, Intent,

and Contributory Infringement. Most Cited Cases In asserting willful patent infringement, plaintiff must prove, by clear and convincing evidence, that alleged infringer acted in disregard of the patent and had no reasonable basis for believing it had a right to do the

#### [6] Patents 291 227

291 Patents

291 XII Infringement

291XII(A) What Constitutes Infringement

291k227 k. Intent or Purpose, and

Knowledge. Most Cited Cases

Considering the totality of the circumstances, court deciding claim of willful patent infringement is required to consider mitigating or ameliorating factors, including whether alleged infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good faith belief that it was invalid or that it was not infringed.

# [7] Patents 291 227

291 Patents

291XII Infringement

291XII(A) What Constitutes Infringement

291k227 k. Intent or Purpose, and

Knowledge. Most Cited Cases

Alleged infringer's belief, for purposes of claim of willful patent infringement, that patent was invalid or not infringed can be established by showing good faith reliance on the competent advice of counsel.

# [8] Witnesses 410 219(3)

410 Witnesses

410II Competency

410II(D) Confidential Relations and Privileged Communications

410k219 Waiver of Privilege

410k219(3) k. Communications to or Advice by Attorney or Counsel. Most Cited Cases When defendant relies on an advice-of-counsel defense, it must waive its attorney-client privilege at least with respect to the counsel's opinion letters.

# [9] Patents 291 314(2)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k314 Hearing

291k314(2) k. Scope of Inquiry and

Power of Court. Most Cited Cases

Although, absent bifurcation of trial, alleged infringers faced difficult choice between asserting advice-of-counsel defense to claim of willful patent infringement and maintaining attorney-client privilege, alleged infringers were only slightly prejudiced for purposes of their motion for bifurcation. Fed.Rules Civ.Proc.Rule 42(b), 28 U.S.C.A.

# 1101 Witnesses 410 € 198(1)

410 Witnesses

41011 Competency

41011(D) Confidential Relations and Privileged

Communications

410k197 Communications to or Advice by

Attorney or Counsel

410k198 In General

410k198(1) k. In General. Most Cited

Cases

# Witnesses 410 219(3)

410 Witnesses

410II Competency

410II(D) Confidential Relations and Privileged

Communications

410k219 Waiver of Privilege

410k219(3) k. Communications to or Advice by Attorney or Counsel, Most Cited Cases Attorney-client privilege cannot be used as both a sword and a shield.

### [11] Patents 291 292.4

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k292 Discovery

291k292.4 k. Other Matters. Most Cited

<u>Cases</u>

#### Patents 291 5 314(2)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

-- E-Supp.2d

--- F.Supp.2d ----, 2006 WL 1037322 (N.D.III.) (Cite as: --- F.Supp.2d ---)

291k314 Hearing

291k314(2) k. Scope of Inquiry and Power of Court. Most Cited Cases

Alleged infringers did not establish that bifurcation of discovery and trial would promote judicial efficiency in patent infringement action involving claim of willful infringement, given that alleged infringers did not show that they were likely to prevail on the merits of liability issue, and real possibility existed that bifurcation would lead to additional discovery disputes. Fed.Rules Civ.Proc.Rule 42(b), 28 U.S.C.A.

# [12] Patents 291 314(2)

291 Patents

291 XII Infringement 291XII(C) Suits in Equity 291k314 Hearing

291k314(2) k. Scope of Inquiry and

Power of Court. Most Cited Cases

Evidence of liability and willfulness would likely overlap in patent infringement action involving claim of willful infringement, and therefore bifurcation of trial would prejudice patentee, which, along with facing substantial delay in final determination of its action, would be forced to present same evidence in two separate trials. Fed.Rules Civ.Proc.Rule 42(b), 28 U.S.C.A.

# [13] Federal Civil Procedure 170A 1955

170A Federal Civil Procedure 170AXV Trial

170AXV(A) In General

170Ak1954 Separate Trials in Same Action 170Ak1955 k. Grounds and Objections.

Most Cited Cases

When issues to be presented in two trials sufficiently overlap, bifurcation should be denied. Fed.Rules Civ.Proc.Rule 42(b), 28 U.S.C.A.

# 141 Patents 291 227

291 Patents

291XII Infringement

291XII(A) What Constitutes Infringement 291k227 k. Intent or Purpose, and

Knowledge. Most Cited Cases

Pactors considered in determining willfulness of patent infringement include (1) whether alleged infringer deliberately copied the ideas or design of another, (2) whether alleged infringer investigated the scope of the patent and formed a good faith belief that it was invalid or that it was not infringed, (3) alleged infringer's behavior as a party to the litigation, (4) alleged infringers' sizes and financial conditions, (5) closeness of the case, (6) duration of alleged misconduct, (7) alleged infringers' remedial action, (8) alleged infringers' motivation for harm, and (9) whether alleged infringers attempted to conceal their misconduct.

# 15 Patents 291 314(2)

291 Patents

291XII Infringement 291XII(C) Suits in Equity 291k314 Hearing

291k314(2) k. Scope of Inquiry and

Power of Court. Most Cited Cases

Bifurcation of trial was not warranted in patent infringement action, inasmuch as limited prejudice that alleged infringers would suffer, absent bifurcation, due to choice between asserting adviceof-counsel defense to claim of willful patent infringement maintaining and attorney-client privilege could be alleviated by proper jury instructions, whereas prejudice to patentee resulting from delay and being forced to present same evidence twice could not be alleviated except by denying bifurcation. Fed.Rules Civ.Proc.Rule 42(b), 28 U.S.C.A.

Paul H. Berghoff, Brian Richard Harris, Christopher Michael Cayan, Dennis David Crouch, George I, Lee, Jennifer M. Kurcz, Leif R. Sigmond, Jr., Marcus Jay Thymian, Matthew J. Sampson, Michelle Lynn McMullen-Tack, Paul S. Tully, Stephen Richard Carden, McDonnell, Boehnen, Hulbert & Berghoff, Ltd., Steven F. Borsand, Trading Technologies International, Inc., Chicago, IL, for Plaintiff. Raymond C. Perkins, Andrew M. Johnstone, George Carter Lombardi, James M. Hilmert, Winston &

Strawn LLP, Chicago, IL, Gary A. Rosen, Law Offices of Gary A. Rosen, P.C., Philadelphia, PA, for Defendants.

#### MEMORANDUM OPINION AND ORDER

MORAN, Senior District Judge.

\*1 Plaintiff Trading Technologies International, Inc. ("TT") brought an action against defendants eSpeed. Inc., ITSEcco Holdings Limited, and Ecco LLC for patent infringement, including allegations of willful infringement. Defendants eSpeed and Ecco now petition this court to bifurcate the trial into two separate parts: (1) liability, including noninfringement, invalidity and unenforceability; and (2) willfulness and damages. Defendants also move for — F.Supp.2d ——, 2006 WL 1037322 (N.D.III.) (Cite 2s: — F.Supp.2d ——)

bifurcation of discovery, limiting current discovery to issues of liability, and holding off on discovery pertaining to willfulness and damages until completion of the liability trial.

#### DISCUSSION

[1][2][3][4] Federal Rule of Civil Procedure 42(b) authorizes us to bifurcate a trial "in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy." The Seventh Circuit designed a three-step process to determine whether to bifurcate a trial:

First, the trial judge must determine whether separate trials would avoid prejudice to a party or promote judicial economy. Only one of these criteria-avoidance of prejudice or judicial economy-need be met before a court can order separation. Next, the court must be satisfied that the decision to bifurcate does not unfairly prejudice the non-moving party. Finally, separate trials must not be granted if doing so would violate the Seventh Amendment

Houseman v. U.S. Aviation Underwriters, 171 F.3d 1117, 1121 (7th Cir.1999) (internal citations omitted). Although the ultimate decision to bifurcate is within our discretion (id.), because we are expected to act to "secure the just, speedy, and inexpensive determination of every action" (Fed. R. Civ. P. 1), bifurcation remains the exception, not the rule. Telewizja Polska USA, Inc. v. EchoStar Satellite Corp., 2005 WL 2405797, \*4 (N.D.III.2005); A.L. Hansen Mfg. Co. v. Bauer Products, Inc., 2004 WL 1125911, \*2 (N.D.III.2004). Patent cases are no exception to this rule. Clipco, Ltd. v. Ignite Design, LLC, 2005 WL 2861032, \*3 (N.D.III.2005); Pfizer, Inc. v. Novopharm Ltd., 2000 WL 1847604, \*1 (N.D.III, 2000); Real v. Bunn-O-Matic Corp., 195 F.R.D. 618, 620 (N.D.III.2000). The party seeking separate trials has the burden of showing that judicial economy would be served and the balance of potential prejudice weighs in favor of bifurcation. Real, 195 F.R.D. at 620.

In determining whether to bifurcate a trial, courts have looked to judicial efficiency, possibility of needless delay, potential juror confusion, the timing of the request for bifurcation, whether any filing delay was tactical, the overlap of evidence and witnesses between the two trials, and prejudice to each party. <u>Valois of America, Inc. v. Risdon Corp.</u> 1998 WL 1661397, \*3 (D.Conn.1998) (cataloging district court cases).

In this case, defendants contend that bifurcation will limit potential juror confusion, simplify the case, promote judicial economy, and quickly address the issues important to the entire futures trading industry. Most importantly, defendants argue that absent bifurcation and a partial stay of discovery they will be substantially prejudiced. Because this issue is the focus of defendants' argument for bifurcation, we will address it at the outset.

\*2 Defendants suggest that absent bifurcation they will be prejudiced by having to choose between using an advice-of-counsel defense to willful infringement, and prematurely waiving attorney-client privilege. This quandary, recognized in dicta in Quantum Corp. v. Tandon Corp., 940 F.2d 642 (Fed.Cir.1991), has since become popularly known as the "Quantum dilemma." In Quantum, the Federal Circuit stated: "Proper resolution of the dilemma of an accused infringer who must choose between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found, is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege. An accused infringer, therefore, should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found. Trial courts thus should give serious consideration to a separate trial on willfulness whenever the particular attorney-client communications, once inspected by the court in camera, reveal that the defendant is indeed confronted with this dilemma."

# Quantum, 940 F.2d at 643-44,

[5][6][7][8] Defendants currently face the situation imagined in *Quantum*. In charging defendants with willful patent infringement, plaintiff must prove, by clear and convincing evidence, that " 'the infringer acted in disregard of the patent ... [and] had no reasonable basis for believing it had a right to do the acts.' " *American Medical Systems, Inc. v. Medical Engineering Corp.*, 6 F.3d 1523, 1530 (Fed.Cir.1993). Considering the "totality of the circumstances," a court is "required to consider mitigating or ameliorating factors." *Id.* One factor to be considered is "whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good-faith belief

--- F.Supp.2d ----, 2006 WL 1037322 (N.D.III.) (Cite as: --- F.Supp.2d ----)

that it was invalid or that it was not infringed." Read Corp. v. Portec, Inc., 970 F.2d 816, 827 (Fed.Cir.1992), abrogated on other grounds by Markman v. Westview Instruments, Inc., 52 F.3d 967, 975 (Fed.Cir.1995). That belief can be established by showing good faith reliance on the competent advice of counsel. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1191 (Fed.Cir.1998); Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1579 (Fed.Cir.1996). Where a defendant relies on an advice-of-counsel defense, however, it must waive its attorney-client privilege at least with respect to the counsel's opinion letters. See Quantum, 940 F.2d 642. Defendants argue that this places them in an untenable situation-either forego a valid defense to willfulness or waive attorney-client privilege, disclose the letters and provide their adversary with a "roadmap to all [their] defenses and legal theories" (defs' mem. at 4).

\*3 Defendants cite a number of cases wherein a. district court, including this court, opted to bifurcate a patent trial where defendants were faced with a Quantum dilemma. See Aptargroup, Inc. v. Owens-Illinois, Inc., 2003 WL 21557632, \*1 (N.D.III.2003); Sage Products, Inc. v. Devon Industries, Inc., 1994 WL 791601, \*2-3 (C.D.Cal.1994). When such cases were decided, however, the Federal Circuit, and thus the lower courts, were operating under a presumption since overruled, that where the accused infringer did not produce an opinion of counsel to rebut willfulness, the finder of fact may legitimately infer that the accused infringer either failed to obtain an opinion of counsel or obtained an opinion that warned the infringer not to proceed. See, e.g., Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1056 (Fed.Cir.1994). Therefore, an accused infringer faced the choice between waiver of attorney-client privilege and a negative inference that any infringement was indeed willful.

The Federal Circuit disposed of the adverse inference in Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH y. Dana Corp., 383 F.3d 1337 (Fed.Cir.2064). In an effort to protect the attorney-client privilege, the Federal Circuit held that "no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel." 383 F.3d at 1341. Plaintiff argues that the elimination of the adverse inference in Knorr-Bremse alleviates any Quantum dilemma faced by defendants. Defendants, anticipating plaintiff's argument, contend that its Quantum dilemma is not premised upon the now defunct adverse inference.

that <u>Knorr-Bremse</u> does not discuss the Quantum dilemma or bifurcation, and that no case has interpreted <u>Knorr-Bremse</u> to limit <u>Quantum</u>. Specifically, defendants contend that absent bifurcation they "cannot assert an advice of counsel defense (thus risking a willfulness finding) without waiving the privilege (and disclosing its litigation strategy to TT)" (defs' mem. at 6).

Neither the parties, nor this court, could find any case construing the Quantum dilemma in light of Knorr-Bremse. FNI We do not believe that means, as defendants would have us believe, that Knorr-Brense did not affect or alter the Quantum dilemma. The quandary noted in *Quantum* existed in part because the adverse inference imposed on an alleged infringer who did not waive its attorney-client privilege weighed in favor of finding willful infringement. See Translogic Technology, Inc. v. Hitachi, Ltd., 2004 WL 2260606, \*3 (D.Or.2004); F & G Scrolling Mouse, L.L.C. v. IBM Corp., 190 F.R.D. 385, 391 (M.D.N.C.1999). In fact, amicus briefs filed with the Federal Circuit prior to its decision in Knorr-Bremse indicate that the Quantum dilemma, and issues similar to those raised by defendants in this motion, were underlying the decision in Knorr-Bremse. For example, one amicus brief stated concern that the opinion would prematurely disclose trial tactics, settlement-related positions, admissions on different issues, or the identity of expert witnesses. Jennifer K. Bush, John E. Gartman, & Elizabeth I. Rogers, Six Patent Law Puzzlers, 13 Tex. Intell. Prop., L.J. 1, 25 (citing Brief σf Amicus Curiae Generic **Pharmaceutical** Association In Support Of Defendants-Appellants at 3). We believe that the Federal Circuit, in coming to its conclusion in Knorr-Bremse, assessed the considerations of the Quantum dilemma before us today.

\*4 We do not believe, however, that Knorr-Bremse completely eliminated the prejudice to a party facing a Quantum dilemma. Although the failure to obtain an exculpatory opinion of counsel no longer provides an adverse inference or presumption that the opinion was unfavorable, there "continues to be 'an affirmative duty of due care to avoid infringement of the known patent rights of others," " Knorr-Bremse, 383 F.3d at 1345-46. Therefore, an accused infringer still must choose between waiving its attorney-client privilege to disclose a favorable opinion letter from counsel, which would weigh in its advantage in assessing the "totality of the circumstances" in a willful infringement charge, and maintaining its attorney-client privilege, thus undercutting its defense. See Debra Koker, Note, Fulfilling the "Due

Page 6

P.Supp.2d------- F.Supp.2d ---, 2006 WL 1037322 (N.D.III.) (Cite as: --- F.Supp.2d ----)

Care" Requirement after Knorr-Bremse, 11 B.U.J. Sci. & Tech. L. 154, 163 ("By retaining the standard of due care and the totality of the circumstances considerations for finding of willfulness, it is likely that the patent opinion will continue to play a dominant role"); Bush et al., Six Patent Law Puzzlers. 13 Tex. Intell. Prop. L.J. at 26 (arguing that, in light of the affirmative duty of due care, until the Federal Circuit clarifies what evidence can be presented regarding willful infringement, an alleged patent infringer may still face a Hobson's choice in determining whether to disclose opinion letters).

[9][10] Thus, we find that absent bifurcation defendants still face a difficult decision. It is true, however, that counsel always faces difficult tactical decisions in planning an attack or defense. It is also true that attorney-client privilege cannot be used as both a sword and a shield. Verizon California Inc. v. Ronald A. Katz Technology Licensing, L.P., 266 F.Supp.2d 1144, 1148 (C.D.Cal., 2003) (citing Columbia Pictures Television, Inc. v. Krypton Broadcasting of Birmingham, Inc., 259 F.3d 1186, 1196 (9th Cir.2001)). And even prior to Knorr-Bremse-and what we see as an easing of the defendants' quandary-many courts found that the weight of competing prejudices, including a Quantum-style prejudice, weighed in favor of one trial and denied a motion for bifurcation. See Real. 195 F.R.D. 618; Edward Lowe Industries, Inc. v. Oil-Dri Corp. of America, 1995 WL 609231 (N.D.III.1995) (although defendant faced a Quantum dilemma, by waiting until after the close of discovery to waive its attorney-client privilege, it was precluded from asserting an advice of counsel defense); Dentsply Intern. Inc. v. Kaydex, 1994 WL 376276 (N.D.III.1994) (determining that disclosure of attorney's opinions, reviewed in camera, would not so substantially prejudice plaintiff that separate trials were warranted); Johns Hopkins Univ. v. CellPro. 160 F.R.D. 30 (D.Del.1995). Therefore, we find that absent an adverse inference defendants are only slightly prejudiced.

\*5 [11] Next, in assessing whether bifurcation would promote judicial economy, courts have looked to whether the circumstances of the case required "a) a need for voluminous documents to resolve damages issues; b) complex infringement issues; c) multiple patents, infringing products, claim, counterclaims, or parties; or d) the probability that the defendant would prevail on the infringement issue, thereby eliminating the need to address the issue of damages." Real, 195 F.R.D. at 621. Defendants contend that bifurcation would streamline a complicated patent case, avoid

potential juror confusion, and, if plaintiff's patents are held invalid, obviate the need for a time-consuming determination of damages and willfulness. Plaintiff counters by arguing that two separate trials would cause considerable delay-that damages discovery is already underway and the issues in each trial would substantially overlan.

Although defendants' argument that separate trials would promote judicial economy if defendants prevail, is true, they have not demonstrated that such success is likely. Cf. Aptargroup, Inc., 2003 WL 21557632 at \*1 (bifurcating the issues of liability and willful infringement partly because plaintiff's liability case had "taken a real hit from ... [the] Markman construction"). In this case we have yet to determine claim construction, but defendants took "a real hit" in the preliminary injunction hearing. In any case involving a damages determination, it would always be judicially efficient to bifurcate trials should defendants succeed in the liability phase. Bifurcation remains the exception, however, because "filn the event that liability is found, two separate trials with two separate juries at remote times would not serve judicial economy." Real. 195 F.R.D. at 624 (citing Home Elevators, Inc. v. Millar Elevator Serv. Co., 933 F.Supp. 1090, 1092 (N.D.Ga,1996)).

Alternatively, defendants contend that "[e]ven assuming eSpeed and Ecco were to lose on liability, bifurcation would still simplify the litigation, because it would postpone inevitable ancillary litigation regarding privilege to a more convenient time, and simplify the parties' presentations to the jury" (defs' mem. at 2). Postponement of ancillary litigation does not necessarily weigh in favor of bifurcation-simply postponing dispute resolution does not increase judicial efficiency. And, as many courts before us have noted, bifurcation can lead to additional discovery disputes that actually add time and energy to a litigation. See William Reber, LLC v. Samsung Electronics America, Inc., 220 F.R.D. 533, 538 (N.D.III.2004), vacated in part by William Reber. LLC v. Sony Ericsson Mobile, 2004 WL 2535074 (N.D.III.2004); Maxwell Chase Technologies, L.L.C. v. KMB Produce, Inc., 79 F.Supp.2d 1364, 1374 (N.D.Ga.1999); F & G Scrolling Mouse, L.L.C., 190 F.R.D. at 395; THK America, Inc. v. NSK Co. Ltd. 151 F.R.D. 625, 633 (N.D.III.1993). Given the nature of this case thus far, we would not be surprised if the parties engaged in extensive motion practice wrangling over whether certain pieces of discovery were applicable to the liability case or the willfulness/damages case. Thus, we do not think that defendants have carried their burden of establishing

--- F.Supp.2d ---, 2006 WL 1037322 (N.D.III.) (Cite as: --- F.Supp.2d ----)

that bifurcation of discovery and trial would promote judicial efficiency. FN2

\*6 [12][13] We turn now to analysis of potential prejudice to plaintiff should we decide to grant defendants' motion. Plaintiff suggests that it would be prejudiced by the delay caused by bifurcation and the time and expense of duplicating efforts in two separate trials. We have already addressed the issue of delay. With regard to duplication, it is true that where issues to be presented in the two trials sufficiently overlap, bifurcation should be denied. Keyes Fibre Company v. Packaging Corp. of America, 763 F.Supp. 374, 375 (N.D.III. 1991). In this case, defendants suggest that "[t]here is simply no overlap between the respective issues" of liability and willfulness/damages (defs' mem. at 7). Not surprisingly, plaintiff disagrees, pointing to an obviousness defense as an example of issue overlap (plf's response at 7). Although at least one court has expressly stated that raising such issues as obviousness and commercial success are insufficient to show a significant overlap of issues (Princeton Biochemicals Inc. v. Beckman Instruments Inc., 180 F.R.D. 254, 256 (D.N.J.1997)), courts in this district have repeatedly held that bifurcation in similar cases was inappropriate because issues of liability and willfulness/damages do overlap. See William Reber. LLC, 220 F.R.D. at 540; Real, 195 F.R.D. at 625-626 (finding that the question of willful infringement is relevant to both liability and damages); THK America, Inc., 151 F.R.D. at 629 (finding that the issues raised by an obviousness defense would be the "same in significant respects as the evidence relating to damages and, therefore, ought to be presented once rather than twice").

[14] Because willfulness is assessed according to a totality of the circumstances, the Federal Circuit has identified a number of factors to consider in making a willfulness determination. [N] Knorr-Bremse, 383 F.3d at 1343; Read Corp., 970 F.2d at 827-28; Tenneco Auto, Operating Co. Inc. v. Visteon Corp., 375 F.Supp.2d 360, 365 (D.Del.2005). The need to consider all of the factors implies that evidence of liability and willfulness will likely overlap. A.L. 2004 WL 1125911 at \*3 ("much of the evidence establishing the totality of the circumstances will have already been presented in the initial liability phase"). Therefore, like the other courts in this district, we find bifurcation would result in prejudice to plaintiff, who, along with facing a substantial delay in final determination of the action, would be forced to present the same evidence in two separate trials.

[15] Although the limited prejudice against defendants can be alleviated by proper instructions to the jury, the prejudice against plaintiff cannot be alleviated without denying bifurcation (See Real, 195 F.R.D. at 621). Therefore, after careful consideration, we conclude that defendants have failed to carry their burden of establishing the advantages of bifurcation. and we deny their motion.

Filed 06/28/2006

#### CONCLUSION

\*7 For the reasons set forth above, we deny defendants' motion for bifurcation of both the trial and discovery relating to the trial.

> FN1. With the exception of A.L. Hansen, 2004 WL 1125911, at \*3, n. 4. In that case, decided before Knorr-Bremse, the court, in a footnote, made a prediction about the possible effect of Knorr-Bremse on Quantum. The court said, "The en banc Federal Circuit is currently reevaluating this inference. Of course, if the Federal Circuit were to eliminate the propriety of these negative inferences, the force of the **Quantum** dilemma would be greatly reduced."

> FN2. With regard to pre-trial negotiations and discovery, this case appears more complicated than most. We are dealing here with the first of seven patent infringement suits brought by this plaintiff in this district. Unfortunately for defendants eSpeed and Ecco, motions and disputes in their case have been acting as the catalyst for similar motions and disputes in the cases that followed. In the end, however, this is really a case between one plaintiff and related defendants, with claims that defendants infringed two of plaintiff's patents. At its heart, it is not that complicated for a patent case. Therefore, additional issues of juror confusion and simplification of issues do not necessarily come into play.

> FN3. Factors include: (1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer investigated the scope of the patent and formed a good faith belief that it was invalid or that it was not infringed; (3) alleged

Page 8

-- F.Supp.2d ---, 2006 WL 1037322 (N.D.III.) (Cite as: -- F.Supp.2d ---)

infringer's behavior as a party to the litigation; (4) defendants' sizes and financial conditions; (5) closeness of the case; (6) duration of defendants' alleged misconduct; (7) defendants' remedial action; (8) defendants' motivation for harm; and (9) whether defendants attempted to conceal their misconduct.

N.D.III.,2006.

Trading Technologies Intern., Inc. v. eSpeed, Inc. -- F.Supp.2d ---, 2006 WL 1037322 (N.D.III.)

# Briefs and Other Related Documents (Back to top)

- 2006 WL 1045535 (Trial Motion, Memorandum and Affidavit) Trading Technologies International, inc.'s Reply Memorandum in Support of its Motion to Compel the Production of Documents and Things, Responses to Interrogatories, and Depositions (Mar. 29, 2006) Original Image of this Document (PDF)
- 2006 WL 1045533 (Trial Motion, Memorandum and Affidavit) Defendants eSpeed and Ecco's Opposition to Trading Technologies Motion to Compel (Mar. 23, 2006) Original Image of this Document (PDF)
- 2006 WL 1040385 (Trial Motion, Memorandum and Affidavit) GL Trade Americas, Inc. and FuturePath Trading LLC's Reply in Opposition to Trading Technologies International Inc's Motion for a Collective Protective Order (Mar. 2, 2006) Original Image of this Document (PDF)
- 2006 WL 740400 (Trial Motion, Memorandum and Affidavit) Trading Technologies' Opposition to Espeed's Motion to Compel (Feb. 23, 2006)
- 2006 WL 740398 (Trial Motion, Memorandum and Affidavit) Trading Technologies International, Inc.'s motion to Compel the Production of Documents and Things, Responses to Interrogatories and Depositions (Feb. 22, 2006)
- 2006 WL 740399 (Trial Motion, Memorandum and Affidavit) eSpeed and Ecco's Reply in Support of Their Motion to Bifurcate Introduction (Feb. 22, 2006)
- 2006 WL 740397 (Trial Motion, Memorandum and Affidavit) Defendants Gl Trade Americas, Inc.'s and Futurepath Trading Lip's Memorandum of Law in Support of Their Motion for A Protective Order (Feb. 14, 2006)
- 2006 WL 740396 (Trial Motion, Memorandum and Affidavit) Reply in Support of eSpeed and Ecco's Second Motion to Compel (Feb. 13, 2006)
- 2006 WL 740395 (Trial Motion, Memorandum and Affidavit) Trading Techonologies' Opposition to Defendants Espeed and Ecco's Motion to Bifurcate (Feb. 10, 2006)

- 2006 WL 740394 (Trial Motion, Memorandum and Affidavit) Trading Technologies' Opposition to Espeed's Motion to Compel (Feb. 6, 2006)
- 2006 WL 740393 (Trial Motion, Memorandum and Affidavit) Trading Technologies' Memorandum in Support of Its Motion to Enter a Collective Protective Order (Feb. 1, 2006)
- 2006 WL 428154 (Trial Pleading) Trading Technologies' Answer to Defendants Espeed, Inc., Espeed International, Ltd., Ecco LLC, and Eccoware Ltd.'s Amended Counterclaim (Jan. 25, 2006)
- 2006 WL 427541 (Trial Motion, Memorandum and Affidavit) eSpeed and Ecco's Memorandum in Support of Their Motion to Bifurcate (Jan. 23, 2006)
- 2006 WL 428153 (Trial Pleading) Defendants Espeed, Inc., Espeed International., Ltd., Ecco LLC, and Eccoware Ltd.'s Answer, Affirmative Defenses, Amended Counterclaim and Counterclaim to Plaintiff's Second Amended Complaint for Patent Infringement (Jan. 5, 2006)
- \* 2005 WL 3615996 (Trial Motion, Memorandum and Affidavit) Defendant's Opposition to Gary Kemp and Plaintiff's Motion to Quash (Nov. 29, 2005)
- 2005 WL 3615995 (Trial Motion, Memorandum and Affidavit) Trading Technologies' Supplemental Reply in Support of Its Motion to Reassign Related Civil Actions to Judge Moran (Nov. 11, 2005)
- 2005 WL 3615994 (Trial Motion, Memorandum and Affidavit) GL Trade Americas Inc. and GL Trade SA's Opposition to Trading Technologies International, Inc.'s Motion to Reassign (Nov. 8, 2005)
- 2005 WL 3286374 (Trial Motion, Memorandum and Affidavit) Trading Technologies' Reply in Support of its Motion to Reassign Related Civil Actions to Judge Moran (Oct. 28, 2005)
- 2005 WL 3286365 (Trial Motion, Memorandum and Affidavit) Peregrine Financial Group, Inc's Opposition to Trading Technologies' Motion to Reassign (Oct. 18, 2005)
- 2005 WL 3286369 (Trial Motion, Memorandum and Affidavit) Refco Llc'%nl%n Opposition to Trading Technologies' Renewed Motion to Reassign (Oct. 18, 2005)
- 2005 WL 2611768 (Trial Motion, Memorandum and Affidavit) Trading Technologies' Reply to Third Parties Steve Brucato and Catus Technologies' Brief in Opposition to Trading Technologies' Motion to Compel (Aug. 17, 2005)
- 2004 WL 2083806 (Trial Pleading) Complaint for Patent Infringement and Jury Demand (Aug. 12, 2004)

END OF DOCUMENT

# EXHIBIT 4

### REDACTED

# EXHIBIT 5

### REDACTED

## EXHIBIT 6

### REDACTED

# EXHIBIT 7

### Westlaw.

Slip Copy Slip Copy, 2005 WL 3664014 (D.N.J.) (Cite as: Slip Copy)

Page I

#### C

Briefs and Other Related Documents
Only the Westlaw citation is currently available.NOT
FOR PUBLICATION

United States District Court, D. New Jersey.
NOVARTIS PHARMACEUTICALS
CORPORATION, Novartis Pharma AG, and
Novartis International Pharmaceutical Ltd., Plaintiffs,

TEVA PHARMACEUTICALS USA, INC., Defendant. No. Civ.A.05-CV-1887 (DM.

Dec. 30, 2005.

Robert Baechtold, Hugh Barrett, Simon Roberts, Fitzpatrick, Cella, Harper & Scinto, New York City, for Plaintiffs.

Goodwin Procter, Boston, MA, for Defendant.

#### OPINION

#### CAVANAUGH, J.

\*I This matter comes before the Court upon Defendant Teva Pharmaceuticals USA, Inc.'s (Teva) motion to strike Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd.'s ("collectively Novartis") claims related to Teva's detailed statement and request for exceptional case status. For the reasons set forth below, Teva's motion is denied.

#### BACKGROUND

The instant case is a patent infringement action arising under the Hatch-Waxman Act, which governs the approval of generic drugs by the U.S. Food and Drug Administration ("FDA"). Novartis is the owner of United States Patent No. 5, 246, 937 ("the 937 Patent"). Complaint at ¶ 9. Pursuant to the Hatch-Waxman Act, Teva filed an abbreviated new drug application ("ANDA") seeking FDA approval to commercially manufacture famciclovir tablets. Id. at 11. Teva's ANDA application included a certification made pursuant to 21 U.S.C. 355(i)(2)(A)(vii)(IV), (the "Paragraph Certification") with respect to Novartis' 937 patent, Id. at ¶ 13. Teva's Paragraph IV Certification stated that the 937 patent is invalid or would not be

infringed by Teva's application. *Id.* On February 22, 2005, as required by the Hatch-Waxman Act, Teva sent Novartis a notice letter, entitled "Detailed Statement", explaining why Teva's proposed generic version of Novartis' tablets will not infringe upon any valid or enforceable claim of Novartis' patents. *Id.* at ¶ 15.

On April 8, 2005, after receipt of Teva's Notice letter, Novartis filed a complaint against Teva for infringement on the 937 patent on ground that the notice letter was deficient Novartis alleges that Teva's manufacture of famciclovir would constitute direct infringement on one or more of the method claims of the 937 patent. Comp. at ¶ 18. Teva filed an answer to the Complaint on June 3, 2005, asserting counterclaims for invalidity, non-infringement and unenforceability of the 937 patent. Simultaneously, Teva filed the instant motion to strike.

In its moving papers, Teva requests that this Court strike Novartis' allegations in its Complaint that (1) Teva failed to "provide the required detailed statement and legal basis in its notice letter" as required by 21 U.S.C. § 355(j)(2)(B)(ii) of the Drug Price Competition and Patent Restoration Act of 1984 ("the Hutch-Waxman Act") (Complaint ¶ 20, Prayer for Relief ¶ B) and (2) that this is an "exceptional case" entitling Novartis to attorneys fees under 35 U.S.C. § 285 of the patent statute. (Complaint ¶ 21, Prayer for Relief ¶ F). The court will examine each of Teva's requests as to strike in turn.

#### DISCUSSION

#### Detailed Statement

Teva argues that the Federal Circuit's ruling in Minnesota Mining and Manuf. Co. v. Barr Labs., Inc., 289 F.3d 775, 777 (Fed.Cir.2002) ("3M") bars Novartis from pursuing a cause of action based upon a deficient notice letter, and that this Court is therefore precluded from considering Novartis' allegations of a deficient notice letter. As such, Teva is requesting the Court strike paragraph 20 of Novartis' Complaint and paragraph B of the prayer for relief.

Page Z

Ship Copy

Slip Copy, 2005 WL 3664014 (D.N.J.)

(Cite as: Slip Copy)

\*2 In response, Novartis states that it is not asking the court to enforce the Notice Letter statute or declare the Notice Letter insufficient under the statute, causes of action prohibited under 3M. Rather, Novartis avers that the purpose of its allegation of an incomplete or flawed Notice Letter is to support its claim of willful infringement/ litigation misconduct, appropriate under the Federal Circuit's holding in Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1342 (Fed.Cir.2000). Furthermore, Novartis asserts that it has not identified any action it wishes the court to take with regard to the Notice Letter, nor any remedy it may be entitled to as a result of any lack of compliance with the notice statute.

In light of the fact that Novartis' allegations regarding the Notice Letter are in the Complaint to support Novartis' request for exceptional case status, the Court does not find it necessary strike Novartis' allegations regarding the insufficiency of the Notice Letter.

#### **Exceptional Case Status**

Tevat requests that the Court strike those portions of the Complaint that concern Novartis' claim for exceptional case status, on the grounds that the filing of an ANDA cannot support the finding of willful infringement for purposes of awarding attorneys fees under 35 U.S.C. § 285. Teva relies on Glazo Group Limited v. Apotex, Inc., 376 F.3d 1339 (Fed.Cir.2004), where the Federal Circuit found that the evidence presented by Glaxo, which consisted mainly of an ANDA filing, did not support a claim for willful infringement for purposes of awarding attorneys fees.

Under 35 U.S.C. § 285, "the [Clourt in exceptional circumstances may award reasonable attorneys fees to the prevailing party." Furthermore, 35 U.S.C. § 271(e)(4) specifically states that when infringement is based on the filing of an ANDA, "a court may award attorneys fees under Section 285." In Yamanouchi, the Federal Circuit held that a patentee in a ANDA case can recover attorney fees for willful infringement/ litigation misconduct under the appropriate circumstances. 231 F.3d 1339, 1342. Yamanouchi involved a similar pattern of facts as those alleged here: the filing of an ANDA, the Paragraph IV certification, the Notice Letter, and litigation misconduct, and the Federal Circuit found exceptional case status warranted.

Novartis argues that Teva's reliance upon Glaxo is incorrect, and that Yamanouchi controls. This Court agrees. Although Teva is correct in stating that Glaxo stands for the proposition that an ANDA filing, without more. does not constitute willful infringement, it is possible that Novartis may be able to show activity in addition to the ANDA filing to support the issue of wilfulness. As such, under Yamanouchi, Novartis is entitled to proceed with litigation under the current state of the pleadings. If

\*3 In light of the above, Teva's request to strike portions of the Complaint relating to Novartis' request for exceptional case status must be denied.

after discovery the evidence is such that Novartis'

claim cannot be supported, Novartis may consider

voluntarily withdrawing its claim or Teva may renew

#### CONCLUSION

Based on the foregoing, Teva's motion to strike Novartis' claims related to Teva's detailed statement and request for exceptional case status is denied. An appropriate Order accompanies this Opinion.

D.N.J.,2005.

its application.

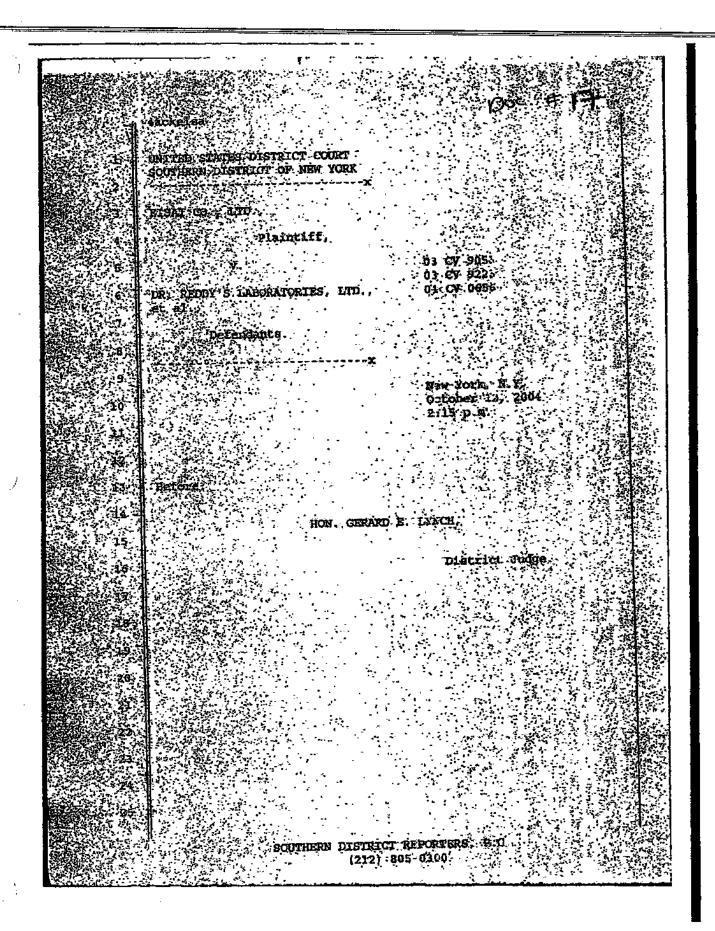
Novartis Pharmaceuticals Corp. Teva Pharmaceuticals USA, Inc. Slip Copy, 2005 WL 3664014 (D.N.J.)

Briefs and Other Related Documents (Back to top)

- 2005 WL 2099258 (Trial Motion, Memorandum) and Affidavit) Reply Brief in Support of Teva's Motion to Strike Plaintiffs' Claims Related to Teva's ""Detailed Statement" and for ""Exceptional Case" (Jul. 27, 2005)
- \* 2005 WL 2099257 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Opposition to Defendant's Motion to Strike Claims (Jul. 13. 2005)
- 2005 WL 1249676 (Trial Pleading) Complaint for Patent Infringement (Apr. 8, 2005)
- 2:05cv01887 (Docket) (Apr. 8, 2005)

END OF DOCUMENT

## EXHIBIT 8



***	The state of the s
<b>Min</b> istral	
	<b>BACKET STATE</b>
	APPEARAUKES
2	
	PIPEDATRICK CHILA
	Accordance for plaintiff He ROMERT L. BARCHTOLD HELLE M. WEIGER
2 miles	BY ROSEPPE L BARCHTOLD
	THE PERSON NAMED IN COLUMN TO SERVICE AND
	JOSEPH M. OMAILEY, JR.
<b>3 1 1 1</b>	
	SOLUTION & CHANNELL
6	actorneys for plaintiff
	BY BRUCE M. MEELER
200	
Marie Title	BOOD LABOUR CROSS PICTOLO ROSENBAUM GREENBERG & SADE
18 (18 )	
	I MV-19900000 C. WEINSTEIN
**************************************	A TOTAL POSS
10.	FOROPOTE PROCESS.
Keren a	according for defendant Teva Pharmaceitical a
LEAN VELV	AND THE PROPERTY OF THE PROPER
Y 100	PREDERICK REIN
5 3 3 12	
	BOTTOTTL FIGS RINGT & MANBECK
	Antomore for defendant Mylan Laboratories
	BY COURTY AC BOXDS
1 2 15	
16	· · · · · · · · · · · · · · · · · · ·
7.	<b>基本文学的 化学人类 化二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十二十</b>
S. A. C.	
1200 4 18	<b>非常是现在,我们们的一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一</b>
<b>Z</b>	
<b>数</b> 数学是44	#F1977 ALLE TO THE TOTAL TO THE TOTAL TO
7 F. Con	
1	
29.	
22.	上的一个人,但是一个人,但是一个人的人,但是一个人的人的人的人,
	事实的意思是可以为了 一个一个一个一个一个一个一个一个一个
200	
200 FF 1 44	
28 2k	
	<b>唯作、秘密表示的主义。                                    </b>
	SOUTHERN DISTRICT REPORTERS, P.C.
72 - No.	(212) · 805-0300 年 子之 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
200 PE 1977	4 T 4 T 100 T 4 T 1 T 1 T 1 T 1 T 1 T 1 T 1 T 1 T 1

dackersa

10

THE CLEEK: Risal V. Dr. Reddy's Laboratories, of all

commet if you would identify yourselves

MR HARCHTOLD: Good aftermoon, your March. Robert.

THE COURT: Mr. Baechtold.

en michin. Good afternoon, your Mosor. David

THE COURT: Do we need Everybody? Who is going to

MR. BARCETOLD: I am, your Honor.

THE COURT, OK, Mr. Haschrold, Who on Defail of the

MR. HASHMALL: Your Honor, good afternoon: David

THE COURT: Mr. Hashmall, are you going to the arothug

MR HASHMALL: Yes, I am, your Honor.

has been discussed at least twice in informal conferences;
leaves me with the impression that we are not signing show:
what me purport to be arguing about in this motion. In this
narrisegs sense, let me ask Mr. Baachtold, ignit at agreed that
if this defendants are entitled to judgment on the pleadings;
the want of a better term; that plaintitts are not entitled to
relegiously and of willful infringement?

4ack**s, 68** 

MR. BARCHTOLD: No. your Ecner, it is not agreed.

THE COURT: Is there such a thing as a declaration of

THE COURT: As a remedy for patent introgenent.

ma marchiold: Certainly a basis for a Clading to willful intringement, and that can result in an award of mutorneys fees.

could make on that a jury could make along the way to grancing relief. We don't in a slip and fall case any that other plaintiff gots damages and also a declaration of causation of declaration of hagingence or anything of the sort. Do wer

margaritation not attorneys' fees.

THE COURT Isn't it more because it is a predicate the specific to be enhanced damages under section 1847

MR. BARCHTORD: No, it is not, your Monor, and that was clear in the recent on banc case in Northway. There there were no damages. That is the case that the Federal Circuit took en hanc to decide whether you could draw all inference transt the aggertion of attorney client privilege. In that takes there were no actual damages, blists was no possibility of a multiplier of actual damages, and the case was

21.

ment book to the district court to determine willful info interior it actually came up on a finding of willful intringement and came back solely as the hand for an attorney itee award

this court. Right, but the court didn't pay that there person to be a judgment of willfulness or that a jury meets up find william ness; did it?

MR. HARCHTOLD: If that is the besis for the expensional case finding it is a necessary finding and it entre le a pury in the case -- I don't recall if Worangy bar A nower put but it there is, that is a jury fame. That is a repartite issue presented to the jury.

THE COURT: I am very puzzled by that . I had been folly and I have even done it, that you put the icone of will blinear to a jury. I haven't thoroughly constribed to be but Sindice in Sand's jury instruction breatism it says that the Federal Circuit has approved of putting will full bess to a jury, though the case that is footnoted for that propositi in shiply one lie which it was put to a jury, apparently, and the Rederal Through dian't say much one way or the other about its and E an not sure I understand why it needs to be that to a vity in a pacent case, particularly if the only reason why it is an deauge is hecouse it is one of many potential predicates for finding an exceptional case and awarding attermeve feed, MR BARCHTOLD: The determinetion of exceptional case

> ABOUTERN DISTRICT REPORTERS, P.C. (212) 805-0300 "

:10:

16

20

232

is placed in the hands of the court, beigh, according to the statistic '90 the question is, if you have a jury trial you then the to make the determination who will decide the underlying fact issue; that is relevant to the question of exceptional case.

THE COURT: But there are a let of fact assues these sight he relevant. Litigation misconduct, for example, is may besit for finding exceptional case, and I have never beard of submitting that to a jury to decide whether there was:

litigation misconduct. There are many things, am sure, in parent law that I haven't heard of, but that would seem very bed would be not very old whether the not very old would be not very old whether the not very old would be not very old whether the not very old would be not very old whether the not very old whether the

MR. BAECHTOLD: Yes, it would, your Boson

THE COURT: I can think of ressons any Willfulness is different in the ordinary patent case: In the undinary patent case: Interpretate the like, do those products infining, and how did to the products like, do those products infining, and how did to the case as sort of naturally allied question; that the intringing product got out on the market. But in this case is any having a harder time seeing why willfulness becomes part of the pass in the same way.

one executors, I think the arswer your bonor, is whether the case is decided by judge or jury. If it is decided by file fidge and the judge makes a finding on exceptional case and I think there is no doubt that we are entitled to

4uckeisa

10

12

prisal for the relief that we can get on the exceptional case the tours has to articulate its findings of fact supporting that one of the allegations we make is that their learning makes a separate arrive and the separate arrive are not, if your Honor decides it was willful, the becomes a basis for finding the exceptional case.

THE COURT. Then why aren't the defendants right that the really all depends on who is the prevailing tacty? I seem, there are a lot of cases in law in which there is a discretionary possibility of awarding attorneys fees and the court has to give its reasons for exercising its discretion, and semestimes those reasons have to do atth questions of fact, what actually happened. But we typically leave that until we see who won, and at that point I suspect that what work is do include some preliminary sense of, does this seem to be really use sided or not

At that point there may be fact questions. Maybe a party says, well, our former counsel misled us or semething, and sugar though this looks like it was a sanchimable, but him litigation position, it wasn't our fault, we got tad legal advice and maybe then there is some inquiry into that

But in the first instance you do the merits; and you don't have discovery up front into what was the other side's lawyers telling it from day one of the lithustion. First icu tind out wan wins, and the winner may have been told by some

12

:18

24

Langer from the beginning, it's a terrible case, you shouldn't even pring it, but if they win, we never hear about that mistage and we never inquire into whether it was a frivolous claim of not, in somebody's opinion, as of when it was brought. It is only when you lose that there may be further accurring of whether your position was ever justified.

MR BARCHTOLD. It is certainly true, would Hobor, that you make the determination of exceptional case after you know who is the prevailing party. But there is nothing that wak that you can't make that concurrently with the decision of the mentra a E can see in some cases it might make series, it might be efficient to separate the two and say we are not even going to think about it until we know who the prevailing party 1. But that always depends on the facts of the case.

. First we can say that Yamanotcki was an approved procedure, so in one sense you can say the court can't go rousby doing what Judge Owen did in Yamanouchi, which was to allow the discovery to go forward, hear the case on the merits, and determine whether or not the certification was baseless and : whether or por the facts at trial which tracked the certification were also baseless. We certainly think it is more efficient to do that.

THE COURT: But is there any indication in Tamanowshi. that the court had ordered discovery on attorneys! opinion; where is a reference in the opinion, I thought, that one party

láckežsą

jout İn

·15

# **17**-

21

MR BAECHTOLD: Page 1347.

Dankury's choice to produce during trial an opinion from it patent attorney. That doesn't indicate that is there were no such choice, if there were no reliance on advice of counse that anyone would get to inquire into what advice Danbury's counsel had given it, with a view to; if Danbury loses, asserting a claim for attorneys' fees on the grounds that hey proceeded in bad faith and willfully contrary to the advice of their lawyers.

MR: BAECHTOLD: Yes. In fact, your Honor in the Yamanouchi case they did not elect to waive privilege and Loydid not elect to rely on the advice of counsel and they withheld every document that was a basis for privilege but one opinion. I was counsel for the plaintiff. I can't tell you what their strategy was in deciding to give up that one opinion while asserting they were not relying muon it. But that it the fact of the case.

THE COURT: Then if I follow the procedure that happened there. I would be on solid ground, it sounds like in not requiring defendants to give up otherwise privileged information, at least at this stage.

MR. RABCHTOLD: I think unless they decide to waive the privilege and rely on it, there is no compulsion to give it

4ackelsa

114

23

up. We might argue about the extent to which providing a sertification is in fact some sort of a waiver.

But the Yamanouchi case made clear that it was the dertification. There was a duty under the Hatch Wagman Ac: to use due care. That was a key factor in finding that the case was exceptional.

THE COURT: . It was objectively baseless.

MR. BARCHTOLD: It was objectively baseless. It may turn out that Teva decides they don't want to rely on addite of commsel. In that case we can't argue that they waited it, they simply can't rely on it. It may well be one of the things we want to explore, within the company was there a recognition that their case was dead on with the Yamanouchi case and it fact the Sertification was baseless, and there was a race to get to the FDA.

The goal in these cases, the plum always is that the generic wants to be the first one to certify, and the first available data for certification was the four-year anniversary of currelient's approval. We got three on that day. So we don't know until we get the discovery, but it may be that (read cobbled this thing together and said let's get a piece of saper on file so we get a priority. If that is so, we think we use entitled to discover that and we think that should be part of the trial on the merits, not something that your topor comes back for three months, six months, a year after you have send

the arguments on the merits.

One of the reasons for believing this is in fact.

Likely is as your Honor knows, at least one defendant has agreed that the invalidity defense is baseless and they have dropped in. Teva is asserting it. We couldn't force them to:

After it They are asserting inequitable conduct as their only defense but it still comes down to efficiency. Thist, there is no material is pertinent to exceptional case one must say in fair game to discovery. So we could ask, do you have an attorney opinion. If they say no, we are going to assert the strokney opinion. If they say no, we are going to assert the attorney opinion. If they say no, we are going to assert the attorney opinion that. But we can ask. If they choose to rely on it, then they produce it.

THE COURT: Let me try and get the answer to what I have to think is a somewhat metaphysical question. You certainly take the position, and I will ask Mr. Reshmall it her agrees although I don't know how he could disagrees that the statute explicitly says that one possible remedian this kind of lawsuit is an award of attorneys' fees for exceptional case.

MR. HARCHTOLD: COTTECT.

THE COURT: I take it your reading of (amanouch) arter glaxo is that one possible way that a 271(e)(ii case can be exceptional is if the infringement was willful.

MR HARCHTOLD: Yes, your Honor, and we say Glarc hag.

4acké isa

14

15

, 17<sup>(1)</sup>

16

not this, is a motion for judgment on the pleadings, and they correctly stated the legal basis for that in their hidef, tat.

you have to show that plaintiff can prove no set of facts of support the claim.

So the question is, does Glaxo say that in an AND case, there is no conceivable set of facts in which anyone could prove villing infringement? But all Glaxo holds is that the mere filing - and in their brief they leave out "mere" constantly - of an ANDA alone can't be the basis for a wittend infringement claim.

The COURT: They also say the mere fining of an application or certification.

MR. BARCHTOLD: Yes, and four times in the Glaxo see they refer to the mere filing. Three times they only say an application. The fourth time they throw in the words for certification in the Glayo case.

The best you could say about that statement is that it is diction, but it clearly has nothing to do with the facts of that case, and in fact they distinguish Famanouthi by saying unlike Yamanouthi, Glavo didn't make a certification.

Yamanouchi, and Yamanouchi itself in the circuit says we don't have to rely on the certification because there was litius ica.

me BARCHTOLD: Yes. Yamanouchi says we don't heat to get there. Glaxo says, if all you've not at the time tilling of

**26** 

18

an ANDA is the failure to get an attorney opinion, which is the only thing the court relied upon — there were no findings in the case they presented — you can't say that's willful that slave says. Glazo doesn't may there is no conceivable basis, and the two district courts who have looked at this so far have said the same thing.

If at some point the defendant wants to make a motion for pumpary judgment, saying OK, we have had discovery now and we sayothat there is no genuine dispute of fact and we are entitled to summary judgment of no willfulness, that is a different animal. What they are trying to do is stop this before we get any discovery.

that world show willfulness? Let me try one out and see it yen can think this, and, if not, you can dire me a letter one. The filing of an application based on a certification that is objectively and subjectively baseless?

Honor because the Yamanouchi case says that the Hatch-Wathard Act, because of the certification requirements that weren in the Glaxo case, imposes a duty of due care on the generic. I gave your Honor an example before. I don't know the appreciation this in discovery, but if people inside the Teva cryanization said you know we have all read the Yamanouchi case, this certification we are filling we don't have a charge on but it

8

**1**5

16

ÍÓ

That the Texa didn't believe in the case, that would establish will the rever find up to the case of the case was objectively baseless, but maybe they had a misguided belief in the case. If we were so show that the Texa didn't believe in the case, that would establish will the rever but if we never get discovery; we rever find out that so one of the facts.

THE COURT: All right, I think that may co. Mr.

I wanted to mention. Your Honor asked about making the Yi wing of exceptional case concurrent with the merits of the case.

That is what happened in Yamanouchi and the circuit approved it. There is also a case called I Tech Systems where the plaintiff was held to have presented a rivolous case, dec belt concurrently with the merits, because that was the most appropriate time for the court to look at those issues.

difference it all makes, and you are saving if This motion were difference it all makes, and you are saving if This motion were drafted or what the defendants are really up to or something is, what is at stake is the subjective mental state of:

executives of the defendants in filing their application.

That's really what this is all about.

MR HARCHTOLD. I would say that's old of the possible

4ackeise

10:

18

24

this court: Because I am not sure how you have discovery linto the objective baselessness of a vising other than by having discovery into the merits of the claim.

know exactly what it says. Your Honor can read it and see that it tracks exactly the Yamanouchi case.

don fineed a willfulness allegation to inquire into the objective merits of the claim. It is either objectively meritorious or objectively meritless or objectively, so meritorious or objectively meritless or objectively. So meritless that it is frivolous. So the only thing that is extra here is the mental state of the defendants, a recognificant within the company at the time that what they were doing was baseless, and when I say that is one example, can't cody up every possible example.

MR DARCHTOLD: But what I am sure is noting to happien, although there has been no motion to sever and step that is exactly what Teva has in mind, and as soon we we start asking discovery questions, if your Honor grants this motion, every question is going to come back that relates to willfulness.

THE COURT: I think the defendants' position now is that they don't need to sever anything, that is just your relevant period, or it becomes relevant only to some attorneys fees olaim later on.

MR. BARCHTOED: That is their position, but we say it

is perfectly appropriate for you to decide exceptional case concurrently with the decision on the merits. In exder to contain we have to have the discovery, and when you reread the revisor's notes they even recommend taking that promptly after the merits decision.

so if it is not decided we are going to have a raft of discovery disputes that are going to come to you, because it each case they will say we are not going to give discovery on that that is only for after there is a determination on the merits.

right that is what this is really about?

about worn Honor. One is simply the issue that the plain of is not entitled to seek a declaration that the defendants, my client or the other defendants, have willfully infringed the patent.

separate relief known as a declaration of wallfulness. Is it is nevertheless the case that they are antitled to sack attorneys' fees, they are entitled to argue that this is a seceptional case under section 285, and willfulness is a possible component, at least, of something being on exceptional case.

MR. HASHMALL: I agree that the prevailing party.

(ackeina

.g.

10

18. 19

20

whether it be Eisai, Teva or Dr. Reddy, has the right to stake an application pursuant to section 285 to have the case declared exceptional and have an award of attorneys fees, and there are a host of cases that talk about the factors that a court should consider in determining whether a case is exceptional or not. I think what the Glaxo v. Apotect holds is that when the active infringement alleged is artificial pursuant to 271(e) (ii), the willfulness component drops out. There cannot be willful infringement — I mean, I don't know how else to read the holding of that case, and I think that what Breat tries to rely upon about whether there has been certification or not is a distinction without difference. The certification or not is a distinction without difference.

can be a distinction without certification.

you 271 (c) (ii), it says it shall be an active infringement to submit that's the preamble to (e) (ii D. An application which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, or the use of which is claimed in a patent, and then it continues; if the purpose of such submission is to obtain approval under the act to engage in the commercial manufacture, use or sale of a drug.

There is a little quirk in these biologics. In the

26

22

in our brief, Biologics did not use to have a list of paterity in the orange book when they were NDA approved and they used not to have to file certification when you wanted to make a generic version of a biologic drug. But you still had to life an NDA and that is what happened in Glako v. Apotec.

Therefore, the court said, we have jurisdiction under 271(e) (11).

discussion in Teva v. Abbott, which we reference in page 3 cf. our reply brief; the court goes through an extended discussion on the history of the biologic and the nonbiologics and the difference in statutory scheme, and concludes, as in the Glaxa rase, that mither way there is jurisdiction for an applification enactment infringement.

as I read it is based on two fundamental principles, one that 271(e)(si) infringements are different than every other patent in the statute. It is an artificial intringement which the court in Eli Lilly defined as simply for the basis of creating jurisdiction in a case in controversy. That raticulate for the federal direction count in a pplies equally whether there is a certification or not. The only issue that is relevant in that you have jurisdiction under 271(e)(ii).

artificial infringement for the purpose of creating litigation

about the validity of the patent. Isn't that the point?

manufacturer could undertake a thorough study of a parent.

decide that it was perfectly valid, get all the scientific and legal advice they can garner, all of which tells them it is perfectly valid, and then they can go in and file an application for the purpose of triggering are expensive lawship in the hope of coercing somebody into settling? These yes haven't much chance of settling if there is a hillion dolling at stake. But theoretically, isn't the concept of a bad fight application a perfectly intelligible concept?

to a powential finding of exceptional circumstances, just the your Honor, if we expect to prevail at trial and we expect to have this court rule that Eisai engaged in inequitable conduct. If at the end of the trial we prevail we intend to ask your. Honor to rule this case exceptional, that they did not do i good faith investigation of their ability to pursue a patent infringe rlaim against my client. It would be the same flipside. I agree that if you rule against us they can seek the obtain a ruling of exceptional circumstances baned upon a baseless, bad faith filing. I don't dispute that. Nor wend

. 15

1.6

· 20

exceptional circumstances if it could be shown that they had no

that different from willfulness, bad faith?

MR. HASHMALL: I read Yamanouchi talking about objectively baseless. Perhaps there is an element of subjective intent -- I am not sure, your Monor.

a court's discretion to say this looks like a very very thin claim, but still if the party had good faith I'm not going to stick them with attorneys' fees? That would be strething hat is bighly relevant, isn't it, whether not only was it base less always a kind of judgment call between you lose and you lose so hadly that we are going to say this is totally baseless? (shit it germane to that, whether the party knew perfectly well it was baseless and had bad motives in doing what it did? That would make it a pretty exceptional case.

MR. HASHMALL: Yes, but if you read Glant, they see careful to distinguish bad faith finding versus willful.

infringement to support exceptional circumstances. Maybe, Inc.

difference as more semantic than substance. It is hard to say,

your Henor, unless you are confronted with a specific Isau. of

discovery or disputed fact relevant to the two issues. Au

certainly Glano's holding is that there can be no willful

infringement in the ANDA case.

15.

: 18

.22

THE COURT: They don't say that there can be no willful infringement in an ANDA case. If they did, in would be much clearer and even Mr. Baechtold's creative exquirent, I think they say that the were filing of an application or certification — I will give you that for this round — can't be the basis for a finding of willfulness.

Now, I don't know what is the difference between in mere filling of something and a filling of something an bad with that is outrageously baseless. But they don't actually say that a filling of an application for certification can have be a component of a finding of willfulness, do they of that kers cast be such a thing as willfulness in an ANDA case? Is here tanguage to that effect?

MR. HASHMALL: This is a quote from I believe pad:

1350. It says "while a myriad of factual coromatances may
give rise to a finding that a case is exceptional for purposes
of 35 05C 28S, this court has limited what types of conduct
might give rise to an award of attorneys' fees for purpose; pt.
section 270(e)(iv)."

to, it seems to me there, is that an ANDA filing or certification cannot be the basis for willful infringement

Yamanoucha this court determined that a baseless and wholil

10

unifustified certification when combined with litigation

again, that may mean that a baseless and wholly unjustified certification standing alone can't be the basic for an exceptional case finding, but it seems to imply quite directly that a baseless and wholly unjustified certification plus is a potential basis.

MR HASHMALL: For exceptional circumstarces, but lot-

is the difference. In other words, if the bests for finding that exceptional case were something like a baseless and who fit bright filed certification plus bad faith, is there anything in either Yanamouchi or Glaxo that says that can't be a basis for a finding of exceptional case?

the decision. One is, I think, premised on the Supreme Court's ruding in Eli hilly that this is an artificial sot and the intringement is really a way of getting jurisdiction before the court. And the second part of the decision is reference to the statutory language itself, and I think it is significant that when the Federal Circuit cited section 271(e) (iv) in its decision, it but out in bold, it bolded that part of the statute that says these are the only remedies hvailable.

to make the point that there cannot be a finding ct will ful

THE COURT: I don't see that, because the part that they emphasize says these are the only remedies except for an award of attorneys' fees under section 285, and there is no willfulness award of attorneys' fees except under 285, is there?

MR. HASHMALL: No. it is typically done under 204, as

THE COURT: 284 is a reason for enhanced damages, and think we are all in agreement that that's not in play in en and anon case.

MR. HASHMALL: Right.

THE COURT: But under 285 is where you get your Altorneys' fees, and willfulness is a subcategory of exceptional case.

MR. MASHMALL: That is where I disagree, with doe respect, your Memor: First, there is no reference to will fulnese in 285.

ings count: There is no reference to w. Il fullness in 284 either. Maybe you patent lawyers can tell me where I. m. missing it in the statute but I haven't found the language.

MR HASHMALL: That is correct. 284 does not apply to a Hadich Workman case in any event. But if Glavo stands for anything, it is that you can't have willful infringement it any

łąckejsa

t A. 17

18

19:

20

".21°

23

. 24 .

ANDA: The only act of the infringement against the defendants is the pereciling of ANDA certification. There is no other alleged act of infringement.

is an not running away from the word whire, " your. Honor. That is the only act of infringement we are alleged to have sigaged in. In response to that, in their papers Eisii points to this notice letter that we sent out to them, and if could just spend a minute, the notice letter is not an act of infringement and is not provided for in 271(e) (ii) but separately provided for in 21 USC 355. If you read bisalist papers, they gay they intend to show that that retice letter was baselese and didn't adequately state the law, etc. . et : Is all that is true; that if you read that autice letter your Honor concludes it is a terrible notice letter, it is not in act of infringement. It is morely sending a letter. The way act alleged against the defendant is the mere filing of the ANNA certification, and Glaxo, by reference to the statute and in reliance on the Supreme Court's discussion of the Legislative bistory of the statute, says you can't on that jurisdictional peg hang a finding of willful intringement. THE COURT, Eli hilly didn't say that.

Mr. HASHMALL: They do talk about limited remedies and Eli Lilly does talk about that this is a jurisdictional conferring statute, it is an artificial act of infringemental simply to give the court jurisdiction to heat what is really a

4ackersa

declaratory judgment action.

maybe famisticard what you said, that a totally frivolous ATA

MR. HASHMALL: I would read that it compled with littigation misconduct seems to be the suggestion in Glass. don't know that the issue has otherwise been resolved.

engaging in litigation misconduct if you filed's tobally well, there is a way. If you filed a totally frivolous, utterly beseless and bad faith application, you are saying there is no possibility of finding that an exceptional cases warranting an award of attorneys' fees to a prevailing.

MR. HASHMALL: I don't know the answer to that question, your Honor. I think the litigation conduct has to play into the court's determination of that issue.

I have not yet discussed the whole issue that has been the folds of Eiszi's papers and the presentation of Mr. Bacchtold, how does all this affect discovery.

THE COURT: Why don't you move on to it.

MR HASHMALL: I think we are satisfied to the relieft we requested in the motion, which is the striking of the paragraphs the dext question is, of course, what is the significance of that. We did not make a discovery motion; rer

13:

has Eisaly so I really don't think that the issue is before your Honor at this point. The parties have not good to a point where we disagreed on any specific discovery request or hal a :meet and confer on it.

THE COURT: But Mr. Baechtold is going to sup right cuit; and subpoena your CEO or somebody, whoever is in charge of making these applications, and he is going to ant him why he you think that we should have our patent declared invalid. that a legitimate question for him to ask?

MR HASHMALL: I think that the cases the overwhelming authorities that we researched and tite in our briefs talk about exceptional circumstances as a colleteral proceeding after there is a determination of a prevailing. party It looks like in Yamanouchi that Judge Owen treated it all an once although it is not clear from the case that I read whiether there was any discovery on the issue. It appears like there was not. I think under 54(d) the judge probably has some discretion to hear it all at once. I wouldn't dispute that.

but I think in this case it would be a terrible idea. Thin is a complicated case. There are a number of defenda ka We have foreign inventors we need to desose. To start. conducting, and it would be mutual, discovery of each other a executives about what you knew when you filed the certainistion and that was the basis and asking Mr. Baechrold's clients matthey think they had a basis for suing my client for

łackelsa

46

infringement, when were they aware of what we think are ho documents, it is going to become a somplete a it is going to swallow up the difficultion of the merits.

higain, this was not, I think, an issue yet to be presented to your Monor, but I think the best way to present in this tase is. Let's have the trial, let's determine the prevailing party, and then if either side wants to make an application under 285 and Rule 54(d), it can be considered by the court.

THE COURT: Can I ask Mr. Baccatold a quick question; that came up in Mr. Hashmall's reply papers at the very end, what might have seemed a throw-away for additional consideration. Do you agree that it is sauce for the goose and that they can take whatever discovery atom be relevant to the theory, whatever theory they have of bad faith or exceptional circumstance because they might turn out to be the prevailing

MR BARCHTOLD: They can take whatever discovery lieves are entitled to, and if we decide not to waive frivilege are not rely on advice of counsel, we won't rely on advice of counsel.

The court But they can query your nonlegal.

executives as to what the basis was other than advice of coursel.

MR, DARCHTOLD: If there was anything other than

advice of counsel they can ask about it. It's an empty paul.

THE COURT: All right, anything else?

Finger on it. Why do they care if it the end of the day we have the same considerations for willfulness as for the exceptional case, and I think the answer just came out. I you leave willfulness in the case, Teva has to move to bifurcate, otherwise they can't resist the discovery. So they are doing an end run around. They are saying leave the exceptional assert in the case, we are just going to say mobody gets discovery on it until you decide who is the prevailing party. That is the real mostvation for this.

artificial act of infringement, and I think your Honor put your finger on that. Until the Hatch-Maxman Act, we didn't meet an artificial act of infringement. When they did the testing to get FDA approval, that was an act of infringement. That was a frigger for litigation. So they made the testing for regulatory purposes immune from a claim of infringement, but they said we've got to litigate these things if there is a real controversy, so we will put in this artificial act.

case at considerable expense, and our position is that we shouldn't have made the certification.

4ackersa

JØ.

that they made.

would somehody make the certification, and the answer is you hope, when I get into discovery, maybe I will make some firsting that will make the case for me. Mr. Hashmall stands here today and says we found all these hot documents. That is the reason people make baseless certifications, to get into the same. In

gamble, because if they do find something, then they wind her they wind have to pay a penalty.

MP BARCHTOID: Exactly. It is a no loss proposit; in if Glamo really says that a generic can never be quilty of infringement, they have a free shot at it. If they find something, they win: If they don't, they still den't have to pay

on what is objectively baseless and what parties telleves by definition, to be a willful infringer you have lost the case. You can't be an infringer unless you lost the case. That means, whatever your reasoning at the beginning it was wrote. However you are not willful if you believed it was right, but you are willful if you believed it was right. In the manouchi, there is no finding that Darbury didn't believe in the merits of its case, as objectively paseless as it was the

4ackeişa

**5**. 5

. 9

11.

12

13

15

.1,7

:1.6

.19

20

31

22

23

24

want the opportunity to show that these people, after resding the family the residual that their case was baseless and they went ahead and filed it anyway.

MR. HASHMALL: Your Honor, one, we did plead
inequitable conduct in the answer before filling the case before
the predoction of documents. It is a very detailed pleading,
the allegation of inequitable conduct. Two, on the lesue if
williful infringement, aside and apart from the issue that re
don't think it is part of the case properly, there is a cause
associated with being declared a willful infringer. It is a
public company. It is in the business of marketing
pharmaceuticals and selling generics around the world. The
simple finding of infringement is viewed by my chieft as a
taint in a sense as a scarlet letter, and therefore it is
important to Teva that that declaration, if it is not
permissible under the law, that it is not one of the available
remedies, not be one of the declarations issued by this cout
at the conclusion of the hearing.

In the ordinary kind of infringement case, the question of willfulness is put to the jury. The jury returns a verdice; and let's say it returns a verdict and checks the box yes for willful infringer. At that point it then becomes a distretionary issue for the court, as to whether there is pring to be enhanced damages or attorneys' fees, and let's say the

15

14 .

× 19:

20...

court decides no. I guess I will ask both sides, does the fudgment read anything more than judgment for praintiff in the amount of A dollars, having been found to infringe the patent? Ion!t that all that happens?

MR. BAKCHTOLD: Of course if the court decides it. there will be a written decision, and the written decision will say, even though the infringement was willful I am not going to award it ...

. But Teva is in the business of making patent challenges. Recently it was published that they have at least 50 cases where they have challenged patents and they have been sued. They are not going to be tainted unless there is a finding that they were willful infringers. So if anything, they should want the issue in the case so that they can be exonerated for their exemplary conduct.

... THE COURT: I am sure they would.

Well, all right, this is very interest ng and enlightening. It does seem to me to be an exercise in how many angels can dance on the head of a pin. I find myself reasonably clear about many of the legal points and still somewhat in doubt as to whether the bottom line is to gran: the motion br deny it, because I think that the actual relief saked by the motion is quite narrow and doesn't really have all the implications that are raised by each side.

The motion appears to me, notwithstanding the lega-

14

15

16

: 17

21

23

theories that it is based on, to seek no more relief than effectively the striking of paragraph 22(b) of the complaint. That is, defendants say that they are entitled to a judgment on the pleadings, that plaintiff cannot be entitled to what that paragraph seeks, which is that a judgment be entered that defendants infringement of the patent in question was and is willful, and plaintiffs are entitled to their reasonable attorneys fees.

So the excent that defendants seek to strike tha demand for attorneys' fees, the motion is clearly denied. because section 271(e) (iv) specifically provides that in this kind of action the plaintiff can be entitled to an award o abbordeys! Fees.

To the extent that that paragraph neeks a judgmen : that infringement was willful, I don't know that there is my authority in any patent case, though I need not go so far icr the court entering such a declaratory judgment. Clearly under section 271(e(iv), there are very specific forms of relief provided, and none of them includes a declaration of willfulness.

So, so far as the dual motion is concerned, it seems. to me that the not very satisfying, not very powerful conclusion is that the motion is granted with respect to the words "that defendants' infringement of the '552 patent was aid is willful but it is denied insofar as it seeks a judgment on

8

12

·£3

15 t

16

17

18

1,9

20 21

22

14

the pleadings that plaintiffs are not entitled to the religion, judgment be entered that plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S. Code section 285, and that seems to me to be a rather straightforward conclusion that doesn't actually get either side that it same to be alwing at.

He parties any guidance on how this litigation is to be conducted. Pirst, there is a significant dispute between the conducted. Pirst, there is a significant dispute between the parties about the interpretation of the Federal Circuit's holding in Glaxo Group Ltd. v. Apoteca Incorporated, 176 F. d. 1399. It is a 2004 case. It is so recent that rehearing as denied just a month ago. In that case, I think the defendants have a good point that it is hard to read this opinion wit but getting a sense that what the Second Circuit may have thin 19th, it was doing, at least some parts of the opinion, was suggesting that there simply can be no finding of willful intringement in what the parties refer to as an ANDA case, a case where the only act of infringement alleged is the filling of a new drug application which is made an infringement by 15 use 271(e) (ii)

At the same time, there are two troubling facts south that reading of the case. The first is, the court doesn't actually say that in so many words, though some of its reasoning suggests that that's what it thinks. What it says

10

31

13

14.

15-

ът. **16** .

io the mere fact of filing an application or contification cannot support a filing of willful infringement. At the same time, the court also distinguished its prior decision in Yamanouchi v. Daubury, 231 F.3d. 1339. Federal Cert 2000. It distinguishes Yamanouchi by saying that in that case, the rount determined that a baseless and unjustified certification, shed combined with litigation misconduct, warranted an exception of case finding, the finding of exceptional case being prerequisite to an award of attorneys' fees under section 185.

That is mystifying to me. The court does not say that a finding of litigation misconduct is weat warrants an exceptional case finding and that the conclusion of the district court in Yamanouchi that the certification was baseless and wholly unjustified was totally relevant to the finding of exceptional case. It seems to think that sometung about a paragraph for certification can be a part of a finding of exceptional case. So what exactly the court means is not as clear as defendants seem to think.

Secondly, it is very hard for me to be leve that the count could mean that a totally baseless and un useified certification made in bad faith can never be the lasis for finding of exceptional case. Indeed, I think it was hard for Mr. Hashmall to answer questions on that because I think it was hard for min to reach a conclusion that such a had faith filing could be disregarded by a court in making inquiry to an

15

16.

13

, 22

exceptional case. I don't know exactly what is the difference between willfulness and bad faith in this setting. I gram that Coppress obviously intended that there be litigation then it passed the Hatch-Waxman Act. It is an act that says le there be litigation, and there was litigation. In that sense the infringement here is artificial, in the sense that it is a trigger for the litigation. At the same time, frivolous triggers for litigation and frivolous litigation are class to isguestin which courts have often recognized that attorney: fees are to be awarded, and it is hard for me to think that a party, who abuses the privilege set forth in the act could be exempt from a finding of exceptional case and award of attorneys fees, if that is what follows.

whether that is called willfulness or is called something else, it does seem intrinsically to involve an inquiry into the subjective as well as objective. If undertified action can warrant an exceptional case finding them it seems to me all the more clear that a subjectively baseless and unjustified certification or application, at east when combined about with other factors, warrants an except chall case finding.

That Brings us to the scope of discovery issue, and here I am just giving guidance. I suppose we may well see some fight when this issue ripens, and maybe it never will ripen, but it does seem to me that it behaves me to give some

4ackelsa

r: 9

10

12

13

14

15.

16

17

18

19

ŚΓ

22

23:

24

guidance on this front. I am sure that Mr. Hashmall is con ect that in the ordinary course an application for attorneys' (ees certainly does not arise until after one party has son on traf. On the other hand, it does not seem to me to make a great hal of sense to have a litigation, have one party win and then conduct what can be a months long discovery process into warious people's subjective state of mind. I dim't think that it swamps the discovery process to acknowledge that issues relating to the state of mind of those who took all the actions that were taken here that might give rise to an exceptional case finding be the subject of discovery. I that is a: more efficient way to proceed, even though it mears both sides 🦪 may have some inquires to make, rather than to wait and then conduct an entirely separate inquiry into one side is motivations, which would mean bringing people that hot jus: for the deposition they are having anyway but for entirely. different discovery. So I don't think anything should pre-lude. either, side from making inquiries that might ultimately be relevant on the grounds that this is a truly exceptional case because one side or the other engaged in some concuct or case side or the other made claims in bad faith in the course of the litigation. I think it has been made clear on both sides Just. such inquiries don't justify the invasion of the attorney client privilege until or unless one side waives the privilege by asserting that advice of counsel is something that

ķ0

15

:: 18

22

: 23

24

is relevant to prove their good faith. So I suppose it is open to either side to say in response to a question of the lik that we have been talking about, witness, the reason why I did tat has to do with advice of counsel and I can't say anything are about it, and that might be the end of it, and there are in other inquiries that were made to turn over to the lawyers and get advice on whether they should make these filings or notificate is what people say, all of this becomes not very much of a distraction and very much a waste of everyone's time.

But I think that is the ruling on the motion, and at least my not particularly learned thoughts on what may turn out to begg rather abstruse question of whether willfulness is a category or not a category for a finding of exceptional case It obviously leaves open any question of whether the willfulness inquiry will ever be put to a jury, and if the ever get there I will have to make up my mind about that . Fut I will say that it seems much less natural to ask a questim whether there was willful infringement about a case of this kind where there has to be a rather artificial definition of what it would mean to willfully infringe. It is greatly "" straightforward. Someone is manufacturing a preduct that it thinks has a patent and asks the jury, and yes, the product. does incorporate, did the defendant do what it cays will aly? Meaning, did it know that there was a putent and did it have any good faith basis for thinking it was on solid ground.

tacketsa

16

17

18

13

20

21

is a little odder in a case like this, where the issue of ws there an infringement is simply did they file an application, and there is automatically an infringement once it is determined that the patent is valid.

So the question of was it willful seem; a more confusing question to ask a jury, and if what we are really do the attorneys' fee inquiry is for the court anyway. If we are going to put that to the jury it may be because somelody persuades me that is actually required, to put a villfulne in question to a jury.

That is getting way shead of us. I saw that only because we did have some discussion of it today. If we ever get there, the parties will no doubt brief it end maybe they will manage to show me my ignorance yet again.

MR MEINSTEIN: Yes, your Honor, This is Lou Weinstein for Reddy.

We have a scheduling issue. We have ruised a number of disputes with Bisai, discovery disputes and privilege disputes and advice of counsel disputes. We have asked for a meet and confer. Last week you wrote a letter asking me ti ask them to set a date to confer. We are having triable setting a date. We are asking the court to help is, since we are all here; to set up a date for a meet and confer.

THE COURT: "I am not everybody a secretary. I take a

4ackelsa

70

13

1.4

15

16

18

, 19

20

21.

22

23

calendar and take a dart and shoot the dart at the calendar, and that a the date. It is not a vary good way of taking a date because it may be very inconvenient for all the law/ers-involvement involved. So I reasonably assume that the law/ers-can work out a date within a reasonable time on their own without my having to resort to such expedience. I am not print to sit here and ask people to block out dates and serve as a scheduling assistant to somebody.

You are going to respond to this?

MR. O'MALLEY: Yes, your Honor. Joe O Malley.

THE COURT: There can't be a good problem with to neck

claim came late last week, on the eve of a fundamental problem. However, there is a missing link. Mr. Weinstein assumes flere will be a dispute that we have to trouble the count with. It raised several issues. We wrote back, and took the time to respond substantively. We want to hear Mr. Weinstein's: responde to our very specific issues that we have raised, and then we will know is there a dispute that we want to trouble the count with.

your claims of privilege are unfounded in the privilege los.

let's set a meet and confer so we know what is inevitable. We want to know his challenge to our privilege, and perhaps are

9"

10

11

13.

1.5 .

16

18

19

20

.21

22

23

that we inadvertently withheld that we can just give to him.

Our position is that we have a letter written, we will get it to Mr. Weinstein today. We want to fur her define the issues so we don't trouble the court unnecessarily and have a mee: and confer very promptly after that.

the court: Let me give my take on that. What you describe, Mr. O'Malley, is reasonable and to some extent I think it is a confer, not a meet. It is within the spirit of the rules that the parties change views before troubling the court. That's the point of a meet and confer. On the other hand; it len't the point that everybody has to do everytain in writing, and take a lot of time. I don't know that Mr. Weinstein has to be under the burden of engaging in a lot of written briefing in order to get his point across. It is abviously a judgment call, how far one goes with this written back and forth before it becomes apparent that one side is stalling or that the parties have intractable disagreement; and I don't know why one party should be precluded from presenting an losue to a court when it thinks the issue is This puts a certain premium in my book on lawyers being reasonable with each other and being reasonable with and file. to the court. I am not particularly happy when parties at works a discovery dispute, or bring a discovery dispute to the carriand at the end of the day, after spending an hour or two bairs

10.

: 12<u>.</u>

13

16

17

18

.19

20

22

- 23

in court thrashing things out, it turns out that really everybody is in agreement, or at least once there is an adult in the room everyone has to admit there is no reasonable familiar for not being in agreement. The court has spent a lot of time accomplished themselves. On the other hand, neither am I very happy if the discovery dispute turns into one in which there is a genuium dispute, and one party has been jerking the other party around, for weeks by engaging in shadow boxing that is expensive and makes all the lawyers happy and all the clients unhappy at I doesn't really advance the ball.

I don't know which description this fails under, but's be clear how this thing is going to be conducted: If the clear how this thing is going to be conducted: If the court what at least in the courthouse is treated as a three-day weekend. OK, they've got a fair opportunity to respond to you. That doesn't necessarily mean that you have to engage in endless — if all they are saying is write me a brief, I will think that is a very fair response on their sairt. But if they are still about to give you a substantive response objecting to what your position is, maybe at that point we do have a ripe issue today. Talk to each other. There are such things as telephones. I encourage informal communication. Figure out what your disagreement is, and if you have a disagreement, bring it to the court and bring is quickly.

4dckeisa

:8

10

11

12.

14

.15

-17

19

20

**2**3

to bring something before the court. The procedure is simile.

You lay out each side a position. Mr. O'Malley has written a letter, he says. You submit yours, and then we are off to the isces for a ruling.

My letter of Wednesday of last week was just enough to set up a meet and confer.

and confer. Then you put it, and if you can't reach some agreement that he is going to turn over item 627, 428 and nothing else, as to the nothing else, come to court. I will be happy to hear you pretty much at a moment's notice.

Anything else?

MR. TULCHIN: Just a point of information, your Fonce, at the end of the court's ruling on the potentiality of putting willfulness to a jury in this case. I wanted to redind the court that there is no jury here.

THE COURT: Well, good.

MR. THECHIN: We stipulate that this is it bench trial;
THE COURT: Then all the easier, because then it would
be incredibly easy for me to finesse the issue of willfulnes,;
if I think it is an exceptional case and there is no dange;
that Glaxo will rear its head. If I don't, then I think it is
the appropriate case for award of attorneys fees and, two I.

4ackeisa think it is not that hard to moot the question of willfulness. So we will see where we wind up, but yes, if that's not even an issue, that I don't see many problems are going to rear their heads on this front from here on in. Thank you very much. \*(Proceedings adjourned) : 18 20 SOUTHERN DISTRICT REPORTERS, P.C. (212) 805-03C0

# EXHIBIT 9

# Westlaw.

Not Reported in F.Supp. Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149 (Cite as: Not Reported in F.Supp.)

Page 1

### Briefs and Other Related Documents

United States District Court, D. New Jersey. Donna Mae MELLON, Plaintiff,

BEECHAM GROUP PLC, et al., Defendants. Civ. No. 86-2179(HAR).

Jan. 3, 1990.

Goldstein, Till, Lite & Reiken by Allyn Lite, and Kenyon & Kenyon by Thomas Creel, for plaintiff. Hopgood, Calimafde, Kalil, Blaustein & Judiowe by Paul H. Blaustein, Jesse Reingold, and Eve Kunen, for defendant Beecham.

### OPINION

## ACKERMAN, District Judge.

\*1 THE COURT: May I have the appearances, please.

MR. CREEL: For Mellon, Thomas Creel.

MR, LITE: Allyn Lite for the plaintiff.

MR. BLAUSTEIN: For Beecham, Paul Blaustein.

MR. REINGOLD: Jesse Reingold.

THE COURT: I've had the pleasure of meeting you before, Mr. Blaustein.

MR. REINGOLD: Jesse Reingold.

THE COURT: I've had the pleasure of meeting you as well.

MS. KUNEN: Eve Kunen.

THE COURT: My pleasure also.

Now, we have two appeals from Magistrate Chesler. Each side is unhappy.

I've read all the papers. I'm ready to decide the matter.

Is there anything you haven't said in the papers in this very voluminous case which has been going on and on and on that you wish to tell me now?

MR. BLAUSTEIN: Your Honor, we've said in our papers our position.

THE COURT: I know you have. I've read them.

MR. BLAUSTEIN: I'm not going-I have nothing else to add, unless you have any questions.

THE COURT: I don't.

Mr. Creel?

MR. CREEL: Your Honor, I have, as Mr. Blaustein does on this. I do call your attention to one case that was cited in our reply brief on the bifurcation question.

THE COURT: The Brad Regan case?

MR. CREEL: The Sherry case, that indicates that the question of wilful infringement is tried to the jury, not to the judge.

THE COURT: Thank you,

This is an appeal of Magistrate Chesler's order, dated September 29, 1989.

The order concerned two matters: Plaintiff Mellon's motion to compel defendants Beecham Group P.L.C. and Beecham, Inc. (Beecham) to produce certain privileged documents and defendants' motion to bifurcate the liability and damages phases of discovery and trial. The order in question granted both motions (the motion to compel the production of documents only in part) and each side herein appeals.

In this suit, plaintiff Mellon asserts that defendants Beecham Group P.L.C. and Beecham, Inc. have infringed a patent belonging to her late husband; this patent is known as the Lewellen invention and concerns a method for suspending two high-yield gels of similar rheological properties in a single The plaintiff asserts that the defendants' product known as Aqua-Fresh infringes upon the Lewellen patent.

In response to plaintiff's claims of patent infringement, the defendant has asserted that the

Not Reported in F.Supp.

Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149

(Cite as: Not Reported in F.Supp.)

plaintiff's patent is invalid based upon prior art, as well as the affirmative defenses of laches and estoppel.

The order being disputed today reads as follows:

1. Discovery and trial shall be bifurcated as follows:

"First, only the liability issues, i.e., validity, infringement, laches and enforceability shall be discovered and tried;

"Second, in the event plaintiff is successful in establishing liability, the damage issues shall be discovered and tried. B. The issue of wilful infringement shall be decided following the trial on liability, as part of the damages trial. 2.A. Plaintiff's request for production of defendants' withheld documents is granted for all documents which are dated prior to March 7, 1984 and;

- \*2 "1. which are communications from counsel and patent agents to either defendant and are communications from either defendant to counsel or patent agents and which mention William B. Lewellen, his widow, his patent or patent applications and/or samples sent by Mr. Lewellen to Beecham; or
- "2. which are documents that reflect or memorialize discussions or communications between either defendant and their counsel or patent agents relating to William Lewellen, his widow, his patent or patent applications and/or samples sent by Mr. Lewellen to Beecham;
- "3, which are internal documents of either defendant, including documents generated by inside counsel of either defendant, including to William Lewellen, his widow, his patent or patent applications and/or samples sent by Mr. Lewellen to Beecham.
- "B. Plaintiff's motion is denied. As to all other documents identified in plaintiff's motion to compel is denied covered by the attorney-client privilege."

The plaintiff argues that in asserting the defenses of laches and estoppel, the defendant has waived any possible privilege concerning documents that would tend to show what exactly the defendant was relying on in making their determination that Aqua-Fresh did not infringe upon the Lewellen invention.

Thus, documents that relate to, e.g., the advice of counsel concerning the legality of patenting and marketing Aqua-Fresh without first obtaining the rights to the Lewellen patent would tend to disprove defendants' claim that they relied on plaintiffs inactivity: The showing which is necessary for the defense of laches.

In turn, defendants argue that they relied on "objective facts"; hence, the test of estoppel can be determined without reference to defendants' "subjective beliefs" based upon the opinions of counsel.

The defendant asserts that it relied upon the advice of counsel concerning the patentability of its own product, (see Beecham's responses to Interrogatories 19 and 20), and that, therefore, this material, if discoverable at all, is only discoverable during the damages phase of the trial insofar as it speaks to the question of wilful infringement.

The parties have characterized the dispute here as centering on the two different views of the applicable law expressed in <u>Southwire Co. v. Essex Group. Inc.</u>, 570 F.Supp. 643 (N.D.III.1983) and A.C. Aukerman Co. v. Miller Formless Co., Inc., 693 F.2d 687 (7th Cir.1982).

Different, who has asserted that there is a conflict between these two cases, urges this Court to follow Aukerman. Plaintiff has suggested that the two cases do not conflict as much as they rely upon different factual predicates. The parties' own research as well as that of this Court reveals that these two cases are the only two cases directly on point. A brief review, however, of the nature of the attorney-client privilege is in order.

The attorney-client privilege imports that a confidential communication between attorney and client will be kept confidential when its discovery is sought. This privilege "foster[s] disclosure and communication between the attorney and client." United States v. Fisher, 692 F.Supp. 488, 490 (E.D.Pa.1988) (quoting In re Grand Jury, Investigation, 599 F.2d 1224, 1235 (3d Cir.1979)), appeal dism'd, 871 F.2d 444 (3d Cir.1989).

\*3 The burden of proving that the privilege exists is on the party asserting the privilege, see, e.g., In re Bevill, Bressler & Schulman Asset Management Corp., 805 F.2d 120, 126 (3d Cir.1986); United States v. Martin, 773 F.2d 579, 584 (4th Cir.1985), because the privilege "stand[s] in derogation of the search for truth and must therefore be 'strictly confined within the narrowest possible limits consistent with the logic of its principle." See

Page 3

Not Reported in F.Supp.

Not Reported in F.Supp., 1991 WL 16494 (D.N.L.), 17 U.S.P.Q.2d 1149

(Cite as: Not Reported in F.Supp.)

Fisher, 692 F.Supp. at 490 and cites therein.

If the communication is disclosed to third parties, then the protection which the privilege provides vanishes. E.g., <u>Hercules, Inc. v. Exxon Corp.</u>, 434 F.Supp. 136, 156 (D.Del.1977) ("The privilege or immunity has been found to be waived only if the facts relevant to a particular, narrow subject matter have been disclosed in circumstances in which it would be unfair to deny the other part an opportunity to discover other relevant facts with respect to that subject matter").

Clients waive the attorney-client privilege by deliberately injecting into the litigation the advice which the clients received from counsel. See <u>Smith v. Alveska Pipeline Serv.</u>, 538 F.Supp. 977, 979 (D.Del.1982), aff'd mem., 758 F.2d 668 (Fed.Cir.1984), cert. denied, 471 U.S. 1966 (1985).

Similarly, the "advice of counsel" exception to the privilege states that where a party asserts as an essential element of their defense that it relied upon the advice of counsel, that party waives the privilege regarding communications pertaining to that advice. See, e.g., Painter v. Marshall Field & Co., 80 F.R.D. 718, 721 (N.D.III.1978).

Under Federal Rule of Civil Procedure 26(b)(1), to be discoverable information must be "relevant to the subject matter involved in the pending application." Moreover, the information sought must pass the threshold of relevancy by relating to an issue that the party seeking the privilege has raised. See Barr Marine Products Co., Inc. v. Borg-Warner Corp., 84 F.R.D. 631 (E.D.Pa.1979).

The crux of the disagreement between the two cases relevant here is whether or not the defenses of laches and estoppel require an inquiry into defendants' state of mind or behavioral predicates.

To prove estoppel, defendants must show four elements: (1) that plaintiff unreasonably and inexcusably delayed enforcement of its rights; (2) that the delay prejudiced the defendant; (3) that the plaintiffs affirmative conduct induced the belief that plaintiff had abandoned its claims against defendants; and (4) that defendants relied on plaintiffs actions to their detriment. See, e.g., Continental Coatings Corp. v. Metco, Inc., 464 F.2d (7th Cir.1972); Aukerman, supra.

The first two elements, i.e., the plaintiff's delay in enforcing his rights and the defendants' consequential prejudice is a sufficient showing for the defense of laches. The Southwire court reasoned that by asserting laches and estoppel, the defendant implicitly asserts that defendant was not relying upon the advice of counsel. Moreover, this somewhat narrow holding supports the conclusion that a defendant's state of mind is discoverable whenever that state of mind is inserted by the defendant into the litigation.

\*4 The defendants argue that to follow Southwire is erroneous, and that this Court should find that Magistrate Chesler erred in following the Southwire precedent, as opposed to that of Auckerman. Defendant's further argue that Magistrate Chesler's presumption, per Southwire, that either defendant relied upon the advice of counsel or it relied upon the plaintiff's delay is implausible.

In reality, defendants argue a cautious and prudent client will seek both the advice of counsel and wait "until a substantial period of time passes" before engaging in the allegedly infringing activity. Thus, defendants argue that their laches defense does not a fortiori preclude reliance on counsel. Defendants further allege that if the logic of the Southwire Court were followed, no manufacturer could ever raise an estoppel defense without first disclosing counsel's opinions.

### The Standard Of Review

This Court has appellate over a magistrate's nondispositive order pursuant to ?? U.S.C. Section 636(b)(1)(A), Federal Rule of Civil Procedure 72(a) and Rule 40(a) of the local rules of the United States. District Court for the District of New Jersey.

Under Third Circuit law, I can set aside a magistrate's decision under Section 636(b)(1)(A) only if it is found to be "clearly erroneous or contrary to law." <u>Cippallone v. Liggett and Group, Inc., 785 F.2d</u>
1108, 1113 (3d Cir.1986)

The United States Supreme Court has stated "a finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. Gypsum Co., 333 U.S. 364, 395 (1948).

Bearing that standard in mind, let me now turn to Magistrate Chesler's order.

Not Reported in P.Supp.

Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149

(Cite as: Not Reported in F.Supp.)

In deciding to compel the defendants to produce those documents which related to the Lewellen patent, Magistrate Chesler found that, "The basic analysis of whether or not the attorney-client privilege has been waived is whether or not you're trying to use the privilege as a shield or as a sword.... When you assert estoppel, you cannot assert that as a defense with one hand and then with the other hand say ... you can't explore our subjective intent.... You're not permitted to do that because you put the subjective intent affirmatively in issue, and you will not be permitted to pick and choose your proofs." Transcript at Page 8.

Moreover, Magistrate Chesler found that, "[b]y asserting estoppel and laches as a defense to liability and also asserting reasonable reliance on the advice of counsel to the wilful infringement claim ... (the defendants have set up) defenses which raise a sufficient hint of inconsistency to warrant permitting plaintiff to fully explore (defendants') defenses." Transcript at Page 14.

In determining that Southwire established the parameters under which discovery of this material may be ordered, the Magistrate held that, "Southwire does not just deal with wilful infringement. It says the estoppel defense also ends up constituting a waiver in part. It holds that there is a full waiver under the facts of this case where you set up inconsistent defenses.... The law is that where you affirmatively inject an issue into the suit in such a manner that those communications then become indeed the most relevant evidence on the issue, but then seek to preclude discovery of it, you're using the privilege as a sword rather than a shield." Transcript at Pages 16 and 19.

\*5 As the defendants' reply brief indicates, the narrow question currently before the Court is whether this Court should follow Southwire or Aukerman, given the absence of applicable Third Circuit or The parties agree, and it is Federal Circuit law. indeed indisputable that if Magistrate Chesler correctly apprehended the state of the law, the facts in this case warrant the result reached in the proceedings below.

Let me begin by noting that the Southwire Court did not perceive Aukerman to stand in firm opposition to the proposition that a subjective inquiry into the defendant's state of mind is justified in certain circumstances. In this regard, the Southwire Court noted the following passage in Aukerman, "This case

can and should be decided on the existing record which excluded defendant's internal thinking, even if we assume that in some other litigation the internal position of the accused infringer might be relevant and discoverable." Southwire, at 648 citing Aukerman at 702.

In Aukerman, the plaintiff brought suit against another alleged infringer. While that suit was pending, the plaintiff conducted license negotiations with the defendant at issue. Moreover, the patentee had given notice that infringement had occurred, threatened enforcement and "proceeded with an extended period of nonenforcement." Aukerman at

Given the totality of the circumstances, the Court felt that plaintiff's affirmative conduct was such that an alleged infringer could reasonably infer that the claim against it had been abandoned. Id.

Finally, the district court denied the plaintiff's motion to compel the production of the attorney-client documents because this, "belated motion came nine months after defendant asserted its claims of privilege and four months after defendant's motion for summary judgment had been filed and after briefs had been submitted on that motion." Id. at 702.

I think it also worth noting that this Appellate Court was determining whether or not lower court had abused its discretion in denying the discovery requested: thus the Court was obligated to give the district court all of the appropriate difference due to a trial court making a discretionary determination.

Aukerman deals with a unique set of factual circumstances, distinguishable from those before this Court, or the Southwire Court. Here, like Southwire and unlike Aukerman, the defendant has asserted that it relied upon the advice of counsel in making its defense to a claim of wilful infringements.

As Magistrate Chesler correctly points out, the inconsistency between the two defenses entitles the plaintiff to limited discovery on the advice of counsel, otherwise the defendant would be using the privilege as a sword rather than a shield. Southwire court noted in support of its decision to order production, "Here, in contrast to Aukerman, the record does contain some support for Southwire's contention that Essex relied on its patent attorneys and not Southwire's inaction." Southwire, at Page 648.

Not Reported in F. Supp.

Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149

(Cite as: Not Reported in F.Supp.)

\*6 The Southwire Court noted, "If Southwire has evidence that Essex actually relied on something other than Southwire's actions or silence, that serves to undercut the inference that Essex seeks to have drawn from its "objective evidence." Id.

The Southwire court correctly perceived that estoppel in general has been construed so as to include questions concerning the defendant's state of mind. See, in this regard, Naxon Telesign Corp. v. Bunker Ramo Corp., 686 F.2d 1258 (7th Cir. 1982), in which the court referred to the following definition of estoppel, derived from the United States Supreme Court in Dickerson v. Colgrove, 100 U.S. 578, 580 (1879): "He who by his language or conduct leads another to do what he would not otherwise have done, shall not subject such person to loss or injury by disappointing the expectations upon which he acted." Naxon, at 1263, n. 8. See also, Minnesota Mining and Mfg. Co. v. Berwick Industries, Inc., 373 F.Supp. 851, 869 (D.N.J.1973).

The dual showing in Southwire, i.e., that the defendant raised the estoppel defense and that the defendant used its patent counsel's opinions to prove reliance upon those opinions in connection with another issue in the case, applies with equal force here. Moreover, this Court agrees with the plaintiff and the Southwire Court in holding that Aukerman does not truly stand for the proposition that a defendant's state of mind is never an issue in the context of an estoppel defense.

The defendant here has deliberately injected its state of mind into the litigation by asserting that it relied upon the advice of counsel. Under the applicable law governing waiver of privilege, I find that the defendant has, by its own litigation and prelitigation behavior, waived any possible privilege concerning advice of counsel referring to the Lewellen patent.

Based on the foregoing, I find that Magistrate Chesler correctly formulated the applicable law, and hereby affirm his order compelling the production of certain privileged documents.

Let me now turn to the Magistrate's order concerning the bifurcation of the damages and liability phases of trial and discovery, which plaintiff Melon is appealing.

In urging that this Court overturn the Magistrate's order. The plaintiff alleges that there are new facts before this Court which the Magistrate did not consider. Specifically, plaintiff's counsel agreed to

defer deposing trial counsel, so as to avoid the issues of possible disqualification of trial counsel. plaintiff suggests that discovery should therefore proceed with the caveat noted above, even if the actual trial is bifurcated.

The other "new" factor is the representation by plaintiff's counsel that the plaintiff had sought to settle the litigation, only to discover that the parties had radically different views. The plaintiff urges that at the least, discovery on damages will facilitate settlement since treble damages are allowable upon a showing of wilful infringement.

\*7 In support of their motion for a bifurcated trial and for a stay on discovery pending the completion of the original trial, the defendants advanced several arguments:

First, the issues in this case are complex and severance will aid the jury and result in substantial savings in both economy and time for the Court and second, the issue of damages is the parties: necessarily complex and time consuming; and third, it is typical for patent cases to proceed in a severed fashion.

The defendants further averred that bifurcation will not violate the defendants' right to a trial by jury. In response, the plaintiff suggests that the prejudice to her cause will be manifest, due to the advanced age of some of the witnesses as well as the fact they are located in England and that the plaintiff will, therefore, incur additional, needless expense were discovery to be bifurcated.

The plaintiff suggests that the parties in this litigation already engaged in considerable wrangling over whether or not discovery should proceed in a given deposition and that Magistrate Chesler's decision will aggravate this situation.

The plaintiff expressed concern that bifurcation will entail further confusion over specific deposition questions or document requests. The plaintiff also maintains that there is nothing inherently complex about damages in this case, that in fact any discovery concerning damages will cover the same witnesses deposed during the liability phase and that Beecham's sales and profit data are relevant both to a determination of validity and of wilful infringement.

Finally, the plaintiff argues that the defendant has the burden of proof and that the defendant has not put forth specific reasons justifying bifurcation.

Not Reported in F.Supp.

Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149

(Cite as: Not Reported in F.Supp.)

noted before, under 28 U.S.C. Section 636(b)(1)(A), I may reconsider the Magistrate's orders if they are "clearly erroneous or contrary to law." Decisions on discovery matters are left to the sound discretion of the judge. See 8 Wright & Miller, Civil Practice and Procedure, Section 2040.

Accordingly, only if the Magistrate's orders constituted an abuse of discretion, may I reconsider them. I may not substitute my judgment for that of the Magistrate because the test is not whether I would have ruled the same way in the first instance. Nonetheless, I must examine the basis of the Magistrate's exercise of discretion.

The Third Circuit has noted in an analogous context that there is the equivalent of an abuse of discretion "if the trial court has not held the defendants to their proper burden or has clearly erred in weighing the factors to be considered." See Reyno v. Piper Aircraft Co., 630 F.2d 149, 160 (3d Cir. 1980), rev'd on other grounds, 70 L.Ed.2d 419 (1982) (forum non conveniens discretionary determination).

Similarly, Judge Wisdom, in his dissent in <u>In re Unterweser Reederei, GMBH, 428 F,2d 888 (5th Cir.1970)</u>, rev'd sub nom., <u>M/S Bremen v. Zapata Off-Shore Co.</u> 407 U.S. 1 (1972) commented "It is truism that we do not observe an exercise of discretion that was misled by an erroneous view of the law." 428 F,2d at 907.

\*8 I also should add, as I stated earlier and I want to repeat, from the Gypsum case, supra, that a finding is clearly erroneous, although there is evidence to support it, the reviewing court, to the entire evidence, is left with the definite and firm conviction that a mistake has been committed.

I believe that the Magistrate erred in making the decision that he did, in making a mistake. I first note that Rule 42(b) of the Federal Rules of Civil Procedure specifically provides the district court with discretion to separate issues for trial in furtherance of convenience, or to avoid prejudice, or when separate trials will be conducive to expedition or economy.

It should be noted, at the outset, that back in April of 1988, in declining to bifurcate this same trial along the validity and infringement lines, I specifically noted that a piecemeal trial on separate issues involved in one suit is not necessarily in the interest of swift, economical and nonprejudicial justice. See Wright and A. Miller, <u>Federal Practice and Procedure</u>, Section 2388 at 279, 283; <u>H.B. Fuller</u>

Co. v. National Starch & Chemical Corp., 595 F.Supp. 622, 625 (D.Del.1984).

Whenever a separation would involve similar witnesses and evidence, the proceedings would be duplicative and any time savings would be speculative. See Reliable Volkswagen Sales & Services C. v. Worldwide Auto Corp., 34 F.R.D. 134, 138 (D.N.J.1963).

The parties seeking bifurcation has the burden of showing that bifurcation is proper in light of the general principle that a single trial tends to lesson the delay, expense and inconvenience to all parties. See McRae v. Pittsburgh Corning Corp., 97 F.R.D. 490, 492 (E.D.Pa.1983).

While my findings concerning infringement and invalidity are distinct from the considerations involved in damages and liability, the reasoning applies with equal force.

The plaintiff has argued that the Lewellen invention was nonobvious and in support of this position the plaintiff will introduce secondary considerations such as the commercial success of the Beecham product and the contacts between Beecham, Lewellen, as well as Lewellen and other companies. The plaintiff persuasively argues that these are the same factors relevant to damages. Such secondary considerations are clearly relevant and probative. See Graham v. John Deere, 383 U.S. 1, 17-18 (1966).

I have lived with this case. I'm not in any way denigrating or deprecating the fact that Judge Chesler has also. He is, as I have often remarked, an extremely able Magistrate. But I find that he hasthat his finding in this regard is clearly erroneous, that he made a mistake here. I do myself, on many occassions and I have appellate courts reminding me of that fact.

I find there will be considerable overlap between the witnesses and the nature of the information sought and that the defendants' argument that reasonable royalty damages are inherently complex are unpersuasive.

\*9 Furthermore, the plaintiff's concern over the advanced age of a number of the relevant witnesses, I believe, supports the plaintiff's position that prudence dictates proceeding with these witnesses now, without waiting until a liability trial has been completed.

Filed 06/28/2006

Not Reported in F. Supp. Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149 (Cite as: Not Reported in F.Supp.)

While not specifically considered by the Magistrate, the plaintiff's agreement to defer deposition and other discovery of defendant's trial counsel should circumvent any potential problems concerning the disqualification of trial counsel.

I'm not going to pass on the Seventh Amendment problem, Mr. Creel. I don't think I have to.

Because I find that the defendant has persuasively argued that there would be a sufficient, and more importantly, significant savings in time and expense, and I say at the risk of being considered immodest or sounding immodest, and hopefully logical, that the logic which I employed in declining to bifurcate infringement and invalidity applies, as I said a little while ago, with equal force, after examining all the issues here.

Therefore, I decided to overrule the Magistrate's opinion in which he bifurcated the trial with respect to damages, liability and stay discovery. It should have been it should not have been the ruling and I reverse it for the reasons stated.

I will ask you, Mr. Creel, if you will-I better ask Mr. Lite, since he's local counsel.

Mr. Lite, will you be kind enough to draw an appropriate order reflecting my findings?

MR. LITE: I certainly will, your Honor. I want to move on with this trial.

D.N.J., 1991. Mellon v. Beecham Group PLC Not Reported in F.Supp., 1991 WL 16494 (D.N.J.), 17 U.S.P.Q.2d 1149

Briefs and Other Related Documents (Back to top)

2:86CV02179 (Docket) (Jun. 04, 1986)

END OF DOCUMENT